Department of Health and Human Services

# Nevada State Health Division

## Infection Control Practices In Nevada


*The Mission of the Health Division is to Promote and Protect the Wellbeing of Nevadans and Visitors to our State by Preventing Disease, Injury and Disability*

***Jim Gibbons, Governor***

***Michael J. Willden, Director***

***Richard Whitley, MS, Administrator***

***Mary Guinan, MD, PhD, State Health Officer***

Rev. 02.12.09

# Table of Contents

## Overview

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported the following day. This raised concerns about an outbreak because SNHD typically confirms four or fewer cases of acute hepatitis C per year. Initial inquiries found that all three persons with acute hepatitis C underwent procedures at the same endoscopy clinic (clinic A) within 35--90 days of illness onset. A joint investigation by SNHD, NSHD, and CDC was initiated on January 9, 2008. The epidemiologic and laboratory investigation revealed that hepatitis C virus (HCV) transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic.

**Source**: Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic --- Nevada, 2007, **MMWR** Weekly, May 16, 2008 / 57(19);513-517.

1. There is not a state statutory requirement for inspecting Ambulatory Surgery Centers (ASCs) on any periodicity. Due to two factors related to the Centers for Medicare and Medicaid Services (CMS), ambulatory surgery centers did not have regular inspections. Currently, group homes are inspected every year because the statute requires it, and homes for individual residential care are inspected every three years because the regulations require it. All other facility types fall into the CMS tiered workload requirements as follows:

    a. The first factor is that Medicare recertification surveys, or inspections, for ambulatory surgery centers are what is called a "Tier 4" activity. That is, you can't do Tier 4 work until you know you'll complete Tier 1, 2, and 3 work.

    b. The second factor is that all inspection resources, with the exception of two facility types, focused on the Tier 1 and Tier 2 work. This practice resulted in ambulatory surgery centers not having full inspections for much longer than the recommended survey interval of 6 years, which is noted on the attached **Frequency Chart**.

2. The **CMS Policy on Accreditation** shows that accrediting bodies also play a role with the survey/inspection process. Ambulatory surgery centers, because they have the option of being accredited by a body that grants deemed status, often do not get inspected by the state agency because CMS has delegated this inspection authority to the accrediting body. The **Accrediting Body Matrix** shows the entities that are authorized by CMS to accredit health facilities; therefore, the responsibility for inspecting these facilities, for the purposes of Medicare, fall to the accrediting bodies.

3. As noted in the box, it was the disease surveillance system that found an issue with Hepatitis C and linked patients to the endoscopy center. The **MMWR** and the **Southern Nevada Health District Press Release** outline how that process worked.

4. There are many disconnects in the health care system. The **State Health Officer Narrative** further describes the issues related to patient safety, and the **System Bubble Chart** as well as the **Issue Bubble Chart** show the intersections of entities in the State of Nevada with each entity having a different role and piece of the puzzle. Further complicating issues, the **Licensing Board Complaint Procedures Matrix** shows how consumers would have to be very sophisticated to understand where to enter the system if they had a concern about the medical practices of a facility or a practitioner.

5. Although efforts were made to bring awareness to this issue through items such as the **Nevada State Health Division Technical Bulletin** and the **Nevada State Health Division News Release and focused facility surveys**, subsequent investigations found that practitioners and facilities were still not adhering to the "one needle, one syringe, one vial" practice and there were problems with disinfection and sterilization. Subsequently, emergency **regulations** were enacted and made effective on July 1, 2008. Since then, permanent regulations have been enacted and are effective as of October 1, 2008.

6. While investigating the incident, the Health Division brought in representatives from the Centers for Disease Control and Prevention. At that time, the CDC worked with Health Division staff to develop a **Focused Infection Control Tool**. The survey staff used that tool to perform focused infection control surveys at all ambulatory surgery centers in Nevada. In addition to the **Focused Infection Control Findings**, the tool revealed two things:

    a. The current assessment process for facilities, which has been designed and driven by the Centers for Medicare and Medicaid Services, relies on assessing whether or not facilities have policies and procedures in place and whether they have been adhered to in carrying out the activities of the facility. It doesn't assess whether the policies and procedures are effective.

    b. The tool, while useful, needs to be designed to collect more detailed information, requires more than "yes" or "no" answers to questions, and needs more time in the field to truly become a useful tool to measure whether or not a facility's practices will limit infections.

    c. To continue to make progress in this regard, the Health Division made a decision to hire a nurse with specific infection control experience, and she is developing systems to have assessments of facilities that are effective in measuring the prevention of infections. The tool is continuing to change, but its data is being

collected in a separate database with the intent that the data can be analyzed over time to assess effectiveness.

d. Information will also be used to develop educational interventions for the improvement of infection control practices.

7. The **Issue Recommendations Matrix** shows other activities that have been initiated by the Health Division in response to the incident.

8. As of February 3, 2009, the BDR list showed the following measures requested as a result of this incident:

   a. SB 70 Revises the provisions requiring inspections of ambulatory care centers and in-office physician clinics (Senator Steven Horsford)

   b. AB 112 Creates Public Health Emergency Committee and Allows Governor to Declare a Public Health Emergency (Legislative Committee on Health Care)

   c. AB 123 Requires permits and accreditation for doctor offices (Legislative Committee on Health Care)

   d. AB 125 Requires accreditation for ambulatory surgery centers (Assemblywoman Gansert)

   e. A BDR to strengthen the authority of the Health Division in responding to emergencies (no bill number yet)

**State of Nevada Health Division**
**Bureau of Health Care Quality and Compliance**
**FACILITY FREQUENCY OF INSPECTION**

| | FACILITY TYPE | FEDERAL | STATE | NAC / NRS |
|---|---|---|---|---|
| 1 | Adult Day Care | | Initial and upon receipt of a complaint | |
| 2 | Agency to Provide Personal Care Services in the Home | | Initial and every 6 years | |
| 3 | Alcohol and Drug Treatment Facilities | | Initial and every 6 years | |
| 4 | Ambulatory Surgery Centers | 5% or at least one each year for non-deemed providers. 5% Validation surveys of deemed ASC's. No more than 7 years elapses between surveys. Additional surveys are completed on average every 6 years for all providers. | Initial and every 6 years | |
| 5 | Businesses that Provide Referrals | | Initial and every 6 years | |
| 6 | Community Triage Center | | Initial and every 6 years | |
| 7 | Comprehensive Outpatient Rehabilitation Facility (CORF) | Initial and 5% or at least 1 per year. | Every 6 years | |
| 8 | Critical Access Hospital (CAH) | Initial<br>Annual<br>No more than 5 years elapses between surveys for any CAH. | | |
| 9 | Critical Access Hospitals | Initial | Already licensed hospitals | |
| 10 | End Stage Renal Dialysis | 10% and no more than 4 years elapses between surveys for any ESRD. | Initial and every 6 years | |
| 11 | Facilities for Modified Medical Detoxification | | Initial and every 6 years | |
| 12 | Facilities for Refractive Surgery | | Initial and every 6 years | |
| 13 | Facilities for Transitional Living for Released Offenders | | Initial and every 6 years | |
| 14 | Facility for the treatment with narcotics: Medication units | | Initial and every 6 years | |
| 15 | Halfway Houses for Recovering Alcohol and Drug Abusers | | Initial and every 6 years | |
| 16 | Home Health Agencies<br>Home Health Agency – Branch | Every 3 years commensurate with the need to assure quality | Initial and every 3 years | |
| 17 | Homes for Individual Residential Care | | Initial and not less than once every three years | NAC 449.15529 |
| 18 | Hospice | Initial and 5% each or at least 1 per year<br>Deemed Hospice – 5% validation surveys | Initial and every 6 years | |
| 19 | Hospital – Non-accredited | Non-accredited = no more than 5 years elapses between surveys for any non-accredited hospital. | Initial and every 6 years | |
| 20 | Hospitals – Accredited | Initial and at least 1% sample validation surveys of accredited hospitals | Initial | |
| 21 | Independent Center for Emergency Medical Care | | Initial and every 6 years | |
| 22 | Intermediate Care Facilities for the Mentally Retarded | Initial and annual | Initial and annual | |
| 23 | Mobile Unit | | Initial and every 6 years | |
| 24 | Nursing Facilities (NF) | Annual (average every 12 months not to exceed 15 months) | Initial and annual | |
| 25 | Nursing Pool | | Initial and every 6 years | |
| 26 | Obstetric Centers | | Initial and every 6 years | |
| 27 | Outpatient Rehabilitation | Based on State Agency judgment 5% or at least 1 per year if there is a risk of quality problems | | |
| 28 | Prisons | | Two surveys per year | |
| 29 | Residential Facilities for Groups<br>(Assisted living facilities or "group care")<br>Includes Residential Care for Alzheimer's endorsement. | | Initial and annual | NRS 449.230(3) |
| 30 | Rural Health Clinics | Every 6 years | Initial and every 6 years | |
| 31 | Skilled Nursing Facilities | Annual (average every 12 months not to exceed 15 months) | Initial and annual | |

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

**Ref: S&C-08-03**

**DATE:** **November 5, 2007**

**TO:** State Survey Agency Directors

**FROM:** Director
Survey and Certification Group

**SUBJECT:** Initial Surveys for New Medicare Providers

**Memorandum Summary**

- The Centers for Medicare & Medicaid Services (CMS), together with States, seek to maintain effective quality assurance in the Medicare program at the same time that:
  - Many new providers are applying to participate in Medicare for the first time;
  - Resources are highly constrained since the President's proposed budget for Survey & Certification (S&C) has not been fully funded for the past three consecutive years;
- Appendix A therefore contains revised survey priorities and procedures to ensure that we obtain greater value from each survey dollar expended, and that CMS' priority structure for survey and certification activities are followed faithfully (see Appendix A);
- CMS longstanding policy makes complaint investigations, recertifications, and other core work for existing Medicare providers a higher priority compared with certification of new Medicare providers. We retain and affirm the advisability of those priorities;
- Providers that have the option of attaining accreditation that conveys deemed Medicare status conducted by a CMS-approved accreditation organization (in lieu of Medicare surveys by CMS or States) are advised that such deemed accreditation is likely to be the fastest route to certification;
- While accreditation by an accreditation organization does not suffice to demonstrate compliance with the special requirements for certain hospitals (such as rehabilitation or psychiatric hospitals or IPPS-excluded units) that receive payment outside of the Inpatient Prospective Payment System (IPPS), proper attestation of compliance with IPPS-exclusion requirements (combined with the accreditation) will permit the State and CMS to act expeditiously on the hospital's application.

## Background

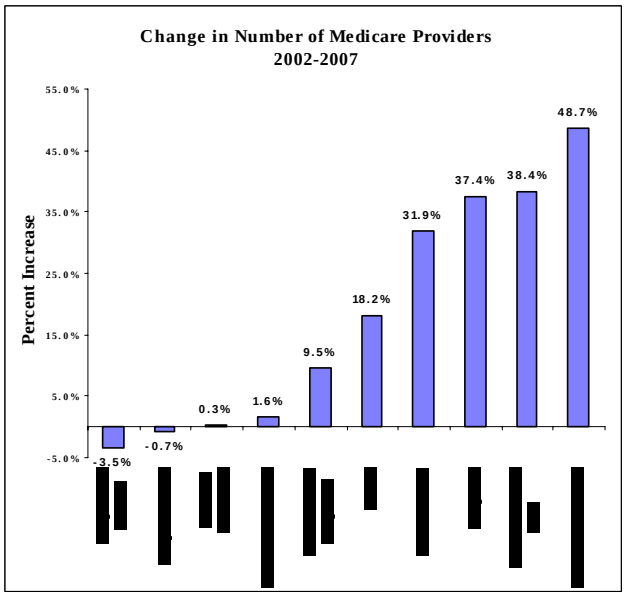
The Social Security Act (the Act) provides for a system of quality assurance in the Medicare program based on objective, onsite, outcome-based surveys by federal and State surveyors. The survey and certification (S&C) system provides beneficiaries with assurance that basic standards of quality are being met by health care providers or, if not met, that remedies are promptly implemented.

CMS accomplishes these vital quality assurance functions under specific direction from the Act and in concert with States, CMS-approved accreditation organizations (AOs), and various contracts with qualified organizations. All CMS or State certification surveys for Medicare must be performed by Medicare-qualified surveyors consistently applying federal regulations, protocols, and guidance. Most types of providers or suppliers seeking to participate in Medicare must first demonstrate compliance with quality of care and safety requirements through an on-site survey.

Initial surveys of new providers or suppliers have become more challenging for four reasons:

***Resource Limitations:*** For the past three consecutive years the final federal budget for Medicare survey and certification has been considerably less than the level requested by the President. The FY 2007 appropriation, for example, was $25 million less than the President's budget request (and lower than FY 2005 levels). Although we remain hopeful that the FY 2008 appropriation will fully fund the President's request, it may be well into the fiscal year before Congress enacts the final FY 2008 budget.

***Many New Providers*:** Many additional providers have been seeking to participate in the Medicare program. Since 2002, for example, the number of Medicare-participating rural health clinics has increased by 48.7%, ambulatory surgical centers by 38.4%, hospices by 37.4%, home health agencies by 31.9%, dialysis facilities by 18.2%, and non-accredited hospitals by 9.5%. The graph to the right portrays the growth between 2002 and 2007 in the number of different providers and suppliers that constitute the main survey and certification workload.




***More Responsibilities*:** Additional survey responsibilities, such as new responsibility for surveys of hospital transplant programs beginning in late 2007, have further stretched survey resources and have increased the need to pay careful attention to survey priorities.

***Anti-fraud Initiatives:*** Growth in the number of certain provider types, particularly home health, has been accompanied by evidence of higher levels of fraudulent activity by a minority of such providers. The Secretary's recent anti-fraud initiatives have called upon survey and certification to conduct additional surveys in certain areas where change of ownership indicates the need for closer review.

## CMS Priorities

Longstanding CMS policy makes complaint investigations, recertifications, and core infrastructure work for existing Medicare providers a higher priority compared with certification of new Medicare providers. CMS directs States to prioritize federal survey functions in four priority "Tiers." Tier 1 consists of statutory mandates, such as surveys of existing nursing homes and home health agencies. Tier 4 consists of other important work, but work that is considered

reasonable to accomplish only if higher priority functions can be accomplished within the federal budget limitations.

Many provider or supplier types (such as hospitals, ambulatory surgery centers, hospices, and home health agencies), have the option of becoming Medicare-certified on the basis of accreditation by a CMS-approved AO instead of a survey by CMS or States. In such cases, the applicants have an alternate route to Medicare certification via CMS' acceptance of the AO's accreditation. While the applicant will pay a fee to the AO for the initial survey, applicants may conclude that the benefits outweigh the expense, particularly the expense of time waiting for a no-cost CMS survey. Similarly, clinical laboratory surveys are not subject to the CMS prioritization structure because the laboratories pay a fee to CMS for the laboratory certification work. For all initial Medicare surveys conducted by CMS or States, there is no cost to the applicant, but the resource limitations described here require that we adhere to a clear sense of priorities in conducting our work.

Most initial surveys for providers or suppliers seeking to participate in Medicare for the first time are prioritized in a lower priority (Tier 4) for CMS and State survey agency (SA) work compared to complaint investigations and recertification of existing providers or suppliers. The increasing severity of S&C resource limitations means that the effect of this longstanding CMS priority on providers and suppliers is more pronounced now than it has been in the past. The situation is different for each State, since some States have seen a large number of new providers seeking Medicare participation while other States have not seen such an increase.

Different providers/suppliers may also experience unique options and circumstances, so that a common policy may have a different impact on different providers. We are therefore refining the CMS policy for initial surveys in order to recognize the different situations being experienced by different providers and suppliers. The revised policy in **Appendix A** accomplishes a number of objectives:

- ***Process for Exceptions***: The revised policy explains the process by which providers or suppliers in certain unique circumstances may request from CMS an exception in their priority assignment.

- ***Higher Priority for Some Unique Situations:*** The "Tier 3" priority is expanded to raise the priority level for providers or suppliers in certain unusual circumstances without needing to request any special exception.

- ***Tier 4 Options:*** The revised policy offers a better explanation of the options available to providers whose application for new participation in Medicare represents a Tier 4 priority for survey and certification. These changes are particularly relevant to hospitals that offer services that are excluded from the Inpatient Prospective Payment System (IPPS). They provide methods by which proper attestation of compliance with IPPS-exclusion requirements (combined with the accreditation) will permit the State and CMS to act expeditiously on the hospital's application.

In the future, CMS will explore additional actions that may strengthen oversight of hospital rehabilitation and psychiatric services, including:

(a) Revising the Medicare hospital Conditions of Participation to include the special requirements for rehabilitation and psychiatric services that are now addressed only in the IPPS-exclusion requirements at 42 CFR 412, and
(b) Conducting onsite surveys for a sample of hospitals that provide rehabilitation or psychiatric services, based on an analysis of the degree to which there may be risk of noncompliance with the IPPS-exclusion requirements. Existing hospitals, as well as new hospitals, would be included in the sample.

**Appendix B** contains an example of content that may be useful in communicating these priorities to applicants.

**Appendix C** contains the addresses for all of the AOs whose accreditation we have deemed for Medicare certification purposes. Please convey this information to prospective providers or suppliers who have the option of deemed accreditation. Please note that some AOs offer accreditation for provider types for which deeming is not an option (either because deeming is not permitted under the law, or because no AO has submitted an approvable application to CMS). Examples include nursing homes and dialysis facilities. For each AO in Appendix C we have listed the provider or supplier types for which the AO's accreditation permits deemed status. If a provider or supplier type is not listed next to the name of a particular AO, then CMS does not deem such accreditation as meeting Medicare requirements.

Some provider types have the deemed accreditation option but an onsite CMS survey has been required to verify compliance with certain payment requirements related to exclusion from the inpatient prospective payment system (IPPS). The IPPS exclusion verification under 42 CFR 412 is a small but important aspect of the accreditation process for which the AO surveys are not deemed. To address this issue we are instituting a time-limited option process to treat the IPPS-exclusion verification for initial applications by signed attestation, the same manner in which such verification is handled for recertifications.

We hope this memorandum will assist States in both prioritizing survey work and in clearly communicating with providers and suppliers to understand:

- The reasons for CMS' priority structure for survey and certification work;
- The options that providers or suppliers have to obtain a survey that can establish their qualification to participate in Medicare;
- The length of time that may elapse before they may be surveyed, with as much certainty as possible given the annual federal budget and resource uncertainties. A clearer sense of the timeline will help providers and suppliers in better planning their efforts.

We request that States make the priority structure in Appendix A, and the procedures for providers that have an AO option, widely known to the provider/supplier community as soon as possible.

We hope the Appendix B potential content may be useful to assist States in offering prospective Medicare providers and suppliers with as much relevant information and timeline clarity as possible.

If you have any questions concerning this memorandum, please contact your CMS Regional Office.

**Effective Date:** The information contained in this memorandum is applicable immediately for all healthcare facilities that rely on CMS survey and certification work. The State Agency should disseminate this information within 30 days of the date of this memorandum.

**Training:** This information should be shared with all appropriate survey and certification staff, surveyors, and the affected provider community.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

## Appendix A
## CMS Priorities for Initial Surveys of Providers and Suppliers Newly Enrolling in Medicare

### I. Priority Exception Requests

***Access to Care Reasons:*** Providers or suppliers may apply to the State survey agency (SA) for CMS consideration to grant an exception to the priority assignment of the initial survey if lack of Medicare certification would cause significant access-to-care problems for beneficiaries served by the provider or supplier. The State SA may choose whether to make a recommendation to CMS before forwarding the request to the CMS Regional Office (RO).

There is no special form required to make a priority exception request. However, the burden is on the applicant to provide data and other evidence that effectively establishes the probability of serious, adverse beneficiary health care access consequences if the provider is not enrolled to participate in Medicare. CMS will not endorse any request that fails to provide such evidence and fails to establish the special circumstances surrounding the provider's request. We expect that such exceptions will be infrequent.

### II. Accreditation Requests

SAs should continue to collect and forward to the CMS RO the certification packets[1] for facilities wishing to participate in Medicare through deemed accreditation, including attestation documents for those facilities seeking first-time IPPS exclusion.

### III. Tier 3

- ESRD Facilities – Due to the unique reliance of dialysis patients on Medicare, and the fact that there are no deemed accreditation options for ESRD facilities, we accord such facilities a higher (Tier 3) priority than most other provider or supplier types.

- Transplant Centers –Transplant centers are accorded the higher Tier 3 priority because there are no CMS-approved accrediting organizations (AOs) for transplant centers. While this may change in the future, CMS has neither received nor approved any AO applications for transplant center accreditation to date. In addition, transplant patients (and donors) rely on Medicare in ways that other patients do not (such as special eligibility provisions for post-operative immuno-suppressive drug coverage when certain otherwise ineligible individuals receive transplants from a Medicare-certified center).

- Hospitals without an AO Option. In this context it is necessary to distinguish the health and safety standards of the certification process for participation in Medicare from verification of compliance with the requirements for exclusion from the Inpatient Prospective Payment System (IPPS).

    - Verification of compliance with IPPS exclusion criteria by whole hospitals or excluded units of short term acute care hospitals is addressed in the discussion of Tier 4 priorities, part V of this Appendix.

[1] Such as the completed provider agreement, applicable civil rights forms, completed worksheets where necessary, copy of the accreditation letter from the AO, etc.

- Surveys for the special psychiatric conditions of participation (CoPs) found at 42 CFR 482.60 through 482.62 will be done as a Tier 3 priority, typically by a CMS contractor. While psychiatric hospitals in general are eligible for deemed accreditation, no AO is approved for verification of compliance for the special psychiatric conditions of participation found at 42 CFR 482.60 through 482.62. We expect that the rest of the hospital's operations would achieve certification through deemed accreditation and that only the non-deemed part would be surveyed by the CMS as a Tier 3 priority.

- ***Critical Access Hospital (CAH) Distinct Part Units:*** A distinct part psychiatric or rehabilitation unit in a CAH must at this time rely on the higher Tier 3 priority, since the AO's currently approved for CAH certification have not been approved for deeming relative to such units. We anticipate that renewal applications by AOs to continue their authority for the CAH program will cover these distinct part units in the future. Only the distinct part unit(s) is eligible for Tier 3 priority, while the rest of the CAH has a deemed accreditation option. We will advise SAs when an AO has been approved to deem the distinct part units.

Note: Conversions of an existing provider under the same provider agreement- is not considered an initial application and the priority for initials does not apply. The provider/supplier types in this circumstance are:

- Conversion of a hospital to a CAH, or a CAH back to a hospital is a conversion (not an initial certification), and at State option may be done as Tier 2, 3, or 4. However, the addition of swing beds as a new service in an existing hospital or CAH is a Tier 4 priority, the same as a new nursing home service would be if it were started by a non-hospital.
- Similarly, the conversion of a Medicaid-only Nursing Facility (NF) to dual-certification (SNF/NF) does not require an initial certification survey and may be done at the State's discretion in accordance with SOM 7002.
- Nursing homes that convert to a Green House certified, resident-centered, culture change environment (which requires new construction).

## IV. Tier 4

Accreditation Options: Initial certifications of all provider/supplier types that have the option to achieve deemed Medicare status by demonstrating compliance with Medicare health and safety standards through a survey conducted by a CMS-approved accreditation organization is a Tier 4 priority. In light of the federal Medicare resource constraints, we consider the cost of initial surveys to be the lowest priority for the Medicare program for those provider and supplier types that have a deemed accreditation option in those States unable to complete the higher-priority Tier 1-3 work.

Provider/supplier types with a Tier 4 priority for initial surveys because the have a deemed accreditation option include:

- Ambulatory Surgical Centers
- Home Health Agencies
- Hospices
- Hospitals
- Critical Access Hospitals

All Others: All other newly-applying providers/suppliers not listed in Tier 3 are Tier 4 priorities, unless approved on an exception basis by the CMS RO due to serious health care access considerations or similar special circumstances (see "Priority Exception Requests" above). The affected Medicare providers/suppliers include:

- Comprehensive Outpatient Rehabilitation Facilities
- Long Term Care Units in Hospitals
- Nursing Homes that do not participate in Medicaid
- Outpatient Physical Therapy
- Rural Health Clinics

## V. Special Provisions for Compliance with IPPS-Exclusion Requirements

With respect to hospitals and CAHs, please note the following policy refinements:

***1. Rehabilitation Hospitals:*** Rehabilitation hospitals are eligible for deemed accreditation, except for verification of the IPPS-exclusion requirements. Procedures for the IPPS-exclusion verifications are described below.

***2. Psychiatric Hospitals:*** Psychiatric hospitals are eligible for deemed accreditation, except for the non-deemed special psychiatric CoPs at 42 CFR 482.60 through 482.62. While survey of the special conditions will be a Tier 3 priority for hospitals that have been otherwise deemed by an accreditation organization, survey for compliance with the rest of the hospital CoPs will remain a Tier 4 priority for CMS since the rest of the hospital survey may be accomplished by an AO.

***3. IPPS-Excluded Rehabilitation Hospitals, and IPPS-excluded Rehabilitation or Psychiatric Units of a Hospital:*** Accreditation organizations do not have authority to verify a hospital's or a hospital excluded unit's compliance with the IPPS exclusion criteria at 42 CFR 412. Currently, annual re-verification of IPPS-exclusion for such excluded hospitals or units in already-certified hospitals is handled by provider self-attestation, but initial verification for first-time IPPS-exclusion has been required via certification surveys by the States.

**Effective immediately we are suspending (until further notice) the requirement for an onsite IPPS-exclusion survey of all hospitals and units seeking first-time IPPS-exclusion (State Operations Manual (SOM) at section 3100 - 3108B), except for providers whose IPPS exclusion has previously been removed. Instead, such providers will be required to submit an attestation and completed Form CMS-437, CMS-437A or CMS-437B, whichever is applicable, indicating that all CMS exclusion requirements are met. Note that these attestation procedures apply to all hospitals and units that are IPPS-excluded.**

In addition to the attestation and applicable Form CMS-437, rehabilitation hospitals and excluded rehabilitation units must also submit evidence of compliance with the medical director requirement. Psychiatric units must submit evidence of compliance with patient assessment and staffing requirements.

The following process will be used for IPPS-exclusion attestation and documentation:

(a) The SA will send to the provider the attestation statement and appropriate CMS-437, along with the standard packet of certification forms and documents, within 10 working days of the earlier of the following two dates:

- Receipt of the provider's letter of intent to open for service and to seek IPPS exclusion; or
- Receipt of the Fiscal Intermediary's recommendation for approval of the 855 application.

(b) In the case of rehabilitation hospitals or rehabilitation units, the SA will also request that the provider attach (to its completed certification packet) documentation that permits verification that the provider has a qualified medical director who meets the regulatory standards at 42 CFR 412.29(f).

(c) In the case of psychiatric units, the SA will also request that the provider attach to its completed certification packet the following information:
- Medical record protocols to permit verification that each patient receives a psychiatric evaluation within 60 hours of admission; that each patient has a comprehensive treatment plan; that progress notes are routinely recorded; and that each patient has discharge planning and a discharge summary.
- A description of the type and number of clinical staff, including a qualified medical director of inpatient psychiatric services and a qualified director of psychiatric nursing services, registered nurses, licensed practical nurses, and mental health workers to provide care necessary under their patients' active treatment plans.

(d) The provider should return the completed certification packet, along with all other requested materials, to the SA no less than 90 days prior to the start of the facility's first or next cost reporting period, as applicable, in order for the RO to have sufficient time to make a determination to approve or deny the provider's IPPS exclusion status. If the provider submits the application less than 90 days in advance, CMS will continue to process the application, but the provider assumes the risk that the RO review may not be completed in time for payment at the excluded rate to start with the first or next cost reporting period.

(e) The SA will act promptly to review the completed packet and will forward it to the RO as soon as possible in order to permit a final certification determination prior to the start of the provider's cost reporting period.

***4. Psychiatric Unit or Rehabilitation Hospital/Unit IPPS Exclusion Removal***: If CMS removes the IPPS exclusion status of a psychiatric unit or a rehabilitation hospital or unit, the hospital may subsequently seek excluded status again. In such cases the hospital is required to operate for at least twelve months under the IPPS while continuing to provide the applicable psychiatric or rehabilitation services that comply with the exclusion requirements.[2] The facility must apply for IPPS exclusion status in the same way as a provider seeking first-time exclusion. **However, in the case of a hospital or unit that has had its IPPS exclusion status removed, the requirement for <u>onsite</u> verification by the SA of compliance with the exclusion criteria for psychiatric or rehabilitation services will remain in force, and such surveys will be a Tier 4 priority.**

[2] The twelve month requirement refers to the cost reporting period, and may be found at 42 CFR 412.25(c) and 412.25(f) for IPPS-excluded units of a hospital, and 42 CFR 412.23(h) and 412.23(i) for rehabilitation hospitals.

## Appendix B - Example of Content for a Potential Provider Communication

Dear _____

We appreciate your request to be certified for participation in the Medicare program. Due to very substantial federal resource limitations, we must currently adhere to a careful priority schedule as we respond to requests from providers that newly seek to participate in Medicare. We hope this letter is helpful to you in understanding your options in this difficult situation.

Two independent and important steps in becoming a Medicare provider are:

> **Form CMS-855:** Form CMS-855 contains background, contact, service, and provider or supplier information that is essential to the approval process. The applications are reviewed and recommended for approval or denial by the Fiscal Intermediaries (FIs) or Medicare Administrative Contractors (MACs) under contract with the Centers for Medicare & Medicaid Services (CMS).
>
> **Certification:** Most types of providers, and some suppliers, are required to demonstrate that they are in full compliance with Medicare quality and safety requirements. This demonstration is accomplished during an onsite survey conducted by trained and qualified surveyors from the State survey agency (SA) pursuant to an agreement with CMS. There is no charge to the provider or supplier for initial CMS surveys or any later CMS recertification survey. The CMS-855 must have been approved and the provider fully operational in order for a survey to be conducted.
>
> Some provider/supplier types have the additional option to be accredited by a CMS-approved accreditation organization (AO), and such accreditation is "deemed" to be equivalent to a recommendation by the SA for CMS certification. The attached list provides contact information on each such AO, as well as information regarding the types of providers/suppliers for which deeming applies. Note that deeming does not apply to some provider types, such as nursing homes and dialysis facilities.

CMS instructs States to place a higher priority on recertification of existing providers, on complaint investigations, and on similar work for existing providers than for initial surveys of providers or suppliers newly seeking Medicare participation. **Due to severe resource limits for Medicare survey & certification functions, in most States few providers that have an AO option will be surveyed by CMS or the State.**

**Short-term acute care hospitals, rehabilitation hospitals, critical access hospitals (but not their distinct part psychiatric and rehabilitation units), home health agencies, hospices, and ambulatory surgical centers** all have the option of deemed accreditation. Applicants have the option of applying to one of the CMS-approved AOs. The attachment to this letter conveys the requisite contact information.

Providers may apply by letter to the SA for CMS consideration to grant an exception to the priority assignment of the initial survey if lack of Medicare certification would cause significant access-to-care problems for Medicare beneficiaries served by the provider or supplier. The SA may choose whether to make a recommendation to CMS before forwarding the request to CMS.

There is no special form required to make a priority exception request. However, the burden is on the applicant to provide data and other evidence that effectively establishes the probability of adverse beneficiary health care access consequences if the provider is not enrolled to participate in Medicare. CMS will not endorse any request that fails to provide such evidence and fails to establish the special circumstances surrounding the provider's or supplier's request.

CMS recognizes that special circumstances apply to certain types of providers or suppliers, and has made special priority allowances for them. Both dialysis facilities and transplant centers, for example, are afforded a higher priority compared to certain other providers/suppliers because there is no AO option available, end-stage renal disease patients and transplant patients have a unique reliance on Medicare for their care, and access is often an issue.

Hospitals that are applying for rehabilitation hospital status or for an IPPS-excluded unit(s) for rehabilitation and/or psychiatric services **and that have (or will have) attained AO accreditation from a CMS-approved AO for their general hospital operations** will be allowed to submit an attestation of compliance with Medicare requirements by their PPS-excluded unit(s). In addition, they will be required to complete a Form-437, Form-437A, or Form-437B, as applicable, in addition to the attestation. This will avoid the need for both an AO accreditation survey and an on-site PPS-verification survey by an SA, since there is no AO option for verification of such IPPS-excluded units. If you are in this situation, please communicate with the SA as early in the process as possible.

We regret that the resource limitations under which we operate may complicate the process of enrolling in Medicare as a certified provider or supplier.

## Appendix C - CMS-Approved Accrediting Organization Contact Information CMS

| Organization | Provider Type | Name | Address | Work Number | Fax Number | E-Mail Address |
|---|---|---|---|---|---|---|
| Joint Commission (JC) | Hospitals, HHAs, Hospice, ASCs, CAHs | Kurtz, Trisha | 601 13th Street, NW<br>Suite 1150N<br>Washington, D.C. 20005 | 202-783-6655 | 202-783-6888 | pkurtz@jcaho.org |
| | Labs | Steffens, Kathie<br><br>Peck, Margaret | One Renaissance Boulevard<br>Oakbrook Terrace, IL<br>60093 | 630-792-5785<br><br>630-792-5287 | 630-792-4885 | ksteffens@jcaho.org<br><br>mpeck@jcaho.org |
| American Osteopathic Association (AOA) | Hospitals, CAHs, ASCs | Reuther, George | 142 East Ontario St<br>Chicago, IL 60611-2864 | 312-202-8060 | 312-202-8360 | greuther@hfap.org |
| | Hospitals, CAHs, ASCs | Beem, Karen | 142 East Ontario St<br>Chicago, IL 60611-2864 | 800-621-1773<br>Ext. 8066 | 312-202-8360 | kbeem@hfap.org |
| | Labs | Thompson, Carol | 142 E. Ontario St.<br>Chicago, IL 60611 | 312-202-8070 | 312-202-8370 | cthompson@hfap.org |
| Community Health Accreditation Program (CHAP) | HHAs, Hospice | Surrency, Gale | 1300 19th Street NW<br>Suite 150 Washington, D.C. 20036 | 202-862-3413<br>800-656-9656, ext. 12 | 202-862-3419 | gsurrency@chapinc.org |
| Accreditation Association for Ambulatory Health Care (AAAHC) | ASCs | Gravesville, Meg | 5200 Old Orchard Road<br>Suite 200<br>Skokie, IL 60076 | 847-853-6073 | 847-853-9028 | mgravesmill@aaahc.org |
| | ASCs | Villanueva, Michon | 5200 Old Orchard Road<br>Suite 200<br>Skokie, IL 60076 | 847-853-6063 | 847-853-9028 | mvillanueva@aaahc.org |
| American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) | ASCs | Pearcy, Jeff | 5101 Washington Street<br>Suite 2F<br>P.O. Box 9500<br>Gurnee, IL 60031 | 847-775-1970 | 847-775-1985 | jeff@aaaasf.org |
| Accreditation Commission for Health Care, Inc (ACHC) | HHAs | Cesar, Tom | 4700 Falls of the Neuse Rd<br>Suite 280<br>Raleigh, NC 27609 | 919-785-1214 | 919-785-3011 | tcesar@achc.org |
| American Society of Histocompatibility and Immunogenetics (ASHI) | Labs | McElroy, Melissa | 90 West County Rd C<br>Suite 300<br>St. Paul, MN 55117 | 651-487-2806 | 651-489-3387 | Melissa@cmehelp.com |

| Organization | Provider Type | Name | Address | Work Number | Fax Number | E-Mail Address |
|---|---|---|---|---|---|---|
| | Labs | Zachary, Andrea<br><br>Leffell, Mary | Johns Hopkins Immunogenetics Laboratory<br>2941 E. Monument St.<br>Baltimore, MD 21205 | 410-955-3600 | 410-955-0431 | aaz@jhmi.edu<br><br>msl@jhmi.edu |
| College of American Pathologists (CAP) | Labs | Daniels, Amy<br><br>Driscoll, Denise | 325 Waukegan<br>Northfield, IL 60093 | 847-832-7471<br><br>847-832-7243 | 847-832-8471 | adaniel@cap.org<br><br>ddrisco@cap.org |
| Commission on Laboratory Accreditation (COLA) | Labs | Harkins, Mina<br><br>Patel, Alka | 9881 Broken Land Pkwy<br>Suite 200<br>Columbia, MD 21046 | 410-381-6581 X 500<br>410-381-6581 X 573 | 410-381-8611 | mharkins@cola.org<br><br>apatel@cola.org |
| American Association of Blood Banks (AABB) | Labs | Sullivan, Judy<br><br>Rapp, Holly | 8101 Glenbrook Rd<br>Bethesda, MD 20814 | 301-215-6540<br><br>301-215-6523 | 301-907-6895 | jsullivan@aabb.org<br><br>Holly@aabb.org |

MMWR™
Morbidity and Mortality Weekly Report
www.cdc.gov/mmwr

Weekly May 16, 2008 / Vol. 57 / No. 19

## Viral Hepatitis Awareness — May 2008

May 2008 marks the 13th anniversary of Hepatitis Awareness Month in the United States. May 19 is World Hepatitis Day, which recognizes the importance of global commitments to prevent liver disease and cancer caused by viral hepatitis. This issue of *MMWR* includes a report on an outbreak of acute hepatitis C associated with unsafe injection practices at an endoscopy clinic and a report on hepatitis C virus (HCV) infections among young injection-drug users. Both reports highlight the role of viral hepatitis surveillance in detecting outbreaks and populations at risk. Development of effective state and local surveillance for acute and chronic viral hepatitis is a public health priority.

HCV infection is the most common bloodborne illness, the leading cause of chronic liver disease, and the primary indication for liver transplantation in the United States. HCV is spread primarily through exposure to infectious blood; injection-drug use is the major contributor to HCV transmission in the United States. Although HCV infection can result in acute illness, most of its effects on the liver, including cirrhosis and liver cancer, are not apparent until years after exposure. Many of the estimated 3.2 million persons living with chronic HCV infection in the United States are unaware of their infection status.

CDC recommends HCV testing for persons at risk (*1*). Persons with HCV infection also should be assessed regularly for severity of liver disease, onset of liver cancer, and the need for treatment. Additional information about viral hepatitis is available at http://www.cdc.gov/hepatitis.

### Reference

1. CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47(No. RR-19).

## Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported the following day. This raised concerns about an outbreak because SNHD typically confirms four or fewer cases of acute hepatitis C per year. Initial inquiries found that all three persons with acute hepatitis C underwent procedures at the same endoscopy clinic (clinic A) within 35–90 days of illness onset. A joint investigation by SNHD, NSHD, and CDC was initiated on January 9, 2008. The epidemiologic and laboratory investigation revealed that hepatitis C virus (HCV) transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic. Health officials advised clinic A to stop unsafe injection practices immediately, and approximately 40,000 patients of the clinic were notified about their potential risk for exposure to HCV and other bloodborne pathogens. This report

**INSIDE**

The *MMWR* series of publications is published by the Coordinating Center for Health Information and Service, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333.

**Suggested Citation:** Centers for Disease Control and Prevention. [Article title]. MMWR 2008;57:[inclusive page numbers].



focuses on the six cases of acute hepatitis C identified during the initial investigation, which is ongoing; additional cases of acute hepatitis C associated with exposures at clinic A might be identified. Comprehensive measures involving viral hepatitis surveillance, health-care provider education, public awareness, professional oversight, licensing, and improvements in medical devices can help detect and prevent transmission of HCV and other bloodborne pathogens in health-care settings.

The objectives of the investigation were to conduct case-finding and review health histories of infected persons, to determine the source of transmission and implement control measures, to identify other patients at risk for exposure, and to assist in development of recommendations to prevent HCV transmission in health-care settings. Persons with acute hepatitis C were interviewed, and blood samples were obtained after these persons gave oral consent. Blood samples were sent to CDC for testing for HCV genotype at the NS5b region and phylogenetic relatedness at the hypervariable 1 region (HVR1) to help determine whether a common source of transmission existed (*1*). Specimens also were tested for other bloodborne infections (hepatitis B virus [HBV]) and human immunodeficiency virus [HIV]). Case-finding activities included SNHD's review of acute hepatitis C surveillance records, cross-matching of local HCV laboratory records with clinic A procedure logs, review of medical records for patients who underwent procedures at clinic A on the same day as HCV-infected persons, and serologic HCV, HBV, and HIV testing of staff. An extensive review of the clinic practices and procedures also was conducted, including observation of several endoscopic procedures and endoscopic reprocessing, observation of anesthesia practices, and interviews with staff members regarding their infection-control practices.

For this investigation, a person was defined as having health-care–associated acute hepatitis C if he or she 1) had symptoms of acute hepatitis within 6 months of having a procedure performed at clinic A during July–December 2007; 2) had laboratory-confirmed HCV infection (antibodies to HCV [anti-HCV]) by enzyme immunoassay (EIA) and recombinant immunoblot assay (RIBA) or EIA with an appropriate signal-to-cutoff ratio for a given assay, or presence of HCV RNA by polymerase chain reaction (PCR) in the absence of acute hepatitis A virus (HAV); and 3) did not have other risks for HCV infection.

In addition to the three persons identified initially, three other persons were determined to have health-care–associated acute hepatitis C, for a total of six cases diagnosed during July–December 2007. One of the three cases was identified by review of surveillance records, another by

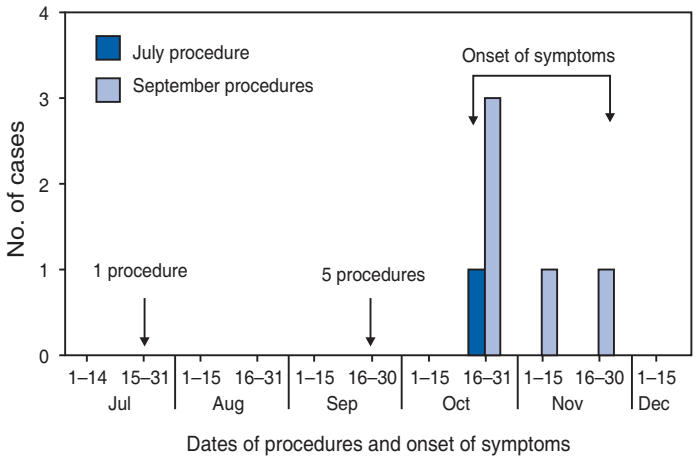
cross-matching local laboratory records with procedure records at clinic A, and the third by physician report after the start of the investigation. The six persons ranged in age from 37 to 72 years; four were female. All had signs and symptoms of acute hepatitis, including jaundice, abdominal discomfort, and laboratory evidence of liver inflammation with alanine aminotransferase (ALT) levels of 552–1,165 units/L.* Four of the six persons required hospitalization as a result of their HCV infection.

The six persons with acute hepatitis C had onset of symptoms in late October 2007 and November 2007, 35–90 days after undergoing procedures at clinic A (Figure 1) and within the typical incubation period of 15–160 days. None had significant risk factors for HCV infection and none had other common exposures. One of the procedures was performed in July 2007; the other five were performed on the same day in September 2007. Five persons (four with procedures on the same day) for whom blood specimens were available at the time of this report had HCV genotype 1a. The four who had procedures on the same day had viral sequences with 99%–100% genetic similarity at HVR1, pointing to a common source of infection. The viral sequence from the HCV-infected person who had the procedure in July 2007 was not genetically related to the other cluster, suggesting a separate transmission incident.

During the 2 days in which persons with health-care–associated hepatitis C had procedures at clinic A, 120 additional persons had procedures at the clinic. HCV test results for those persons are pending. Thirty-eight staff members at the clinic involved in direct patient care were available for testing during the investigation, and none had evidence of previous or current HCV infection. None of the persons with health-care–associated acute hepatitis C and none of the staff tested positive for HBV or HIV infections.

Inappropriate reuse of syringes on individual persons and use of medication vials intended for single-person use on multiple persons was identified through direct observation of infection-control practices at clinic A (Figure 2). Specifically, a clean needle and syringe were used to draw medication from a single-use vial of propofol, a short-acting intravenous anesthetic agent. The medication was injected directly through an intravenous catheter into the patient's arm. If a patient required more sedation, the needle was removed from the syringe and replaced with a new needle; the new needle with the old syringe was used to draw more medication. Backflow from the patient's intravenous catheter or from needle removal might have contaminated the syringe with HCV and subsequently contaminated the vial. Medication remaining in the vial was used to sedate the next patient.

**FIGURE 1. Acute hepatitis C in six persons who underwent endoscopies at clinic A, by dates of procedures and onset of symptoms — Nevada, 2007**



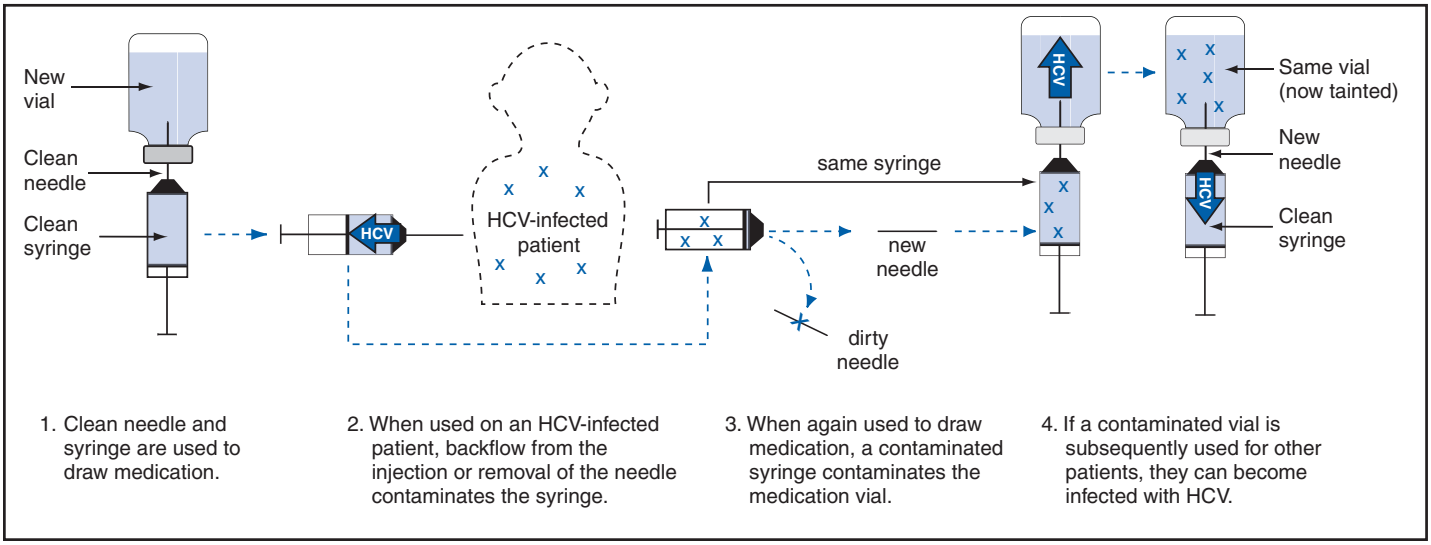

As soon as improper injection practices were observed, health officials advised clinic A to stop these practices and educated staff about the risks. Clinic A is a free-standing private endoscopy clinic in southern Nevada that primarily performed upper endoscopies and colonoscopies (approximately 50–60 procedures a day, 5 days a week). For at least the 4 years that clinic A occupied its existing location, the unsafe injection practices had been commonly used among some staff members who administered anesthesia, according to those who were interviewed. On February 27, 2008, SNHD began notifying approximately 40,000 persons who underwent procedures requiring anesthesia at the clinic from March 1, 2004, through January 11, 2008, via mail and through the media, to undergo screening for HCV, HBV, and HIV infections. Results of this screening are pending.

**Reported by:** *B Labus, MPH, L Sands, DO, P Rowley, Southern Nevada Health District, Las Vegas; IA Azzam, MD, Nevada State Dept of Health and Human Svcs. SD Holmberg, MD, Div of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; JF Perz, DrPH, PR Patel, MD, Div of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases; GE Fischer, MD, M Schaefer, MD, EIS officers, CDC.*

**Editorial Note:** Although case-control studies have not indicated an increased risk for acquiring HCV from medical, surgical, or dental procedures in the United States (*2*), outbreaks of HCV in health-care settings have long been recognized (*3*). These outbreaks have been identified primarily through clusters of temporally related cases detected by routine viral hepatitis surveillance, a method that likely

* The normal ALT range varies according to age, sex, and other factors. An upper limit of 28–55 units/L is generally considered normal.

**FIGURE 2. Unsafe injection practices and circumstances that likely resulted in transmission of hepatitis C virus (HCV) at clinic A — Nevada, 2007**




underestimates the magnitude of transmission. Surveillance for viral hepatitis typically is passive, with little or no capacity to investigate cases suggestive of transmission during health care and determine their cause (*4*). Among persons with acute HCV infections, 60%–70% are asymptomatic (*2*). Additionally, currently available laboratory tests cannot distinguish acute from chronic HCV infection, which makes identifying newly acquired cases difficult.

The investigation described in this report identified six cases of acute hepatitis C in persons who underwent procedures at clinic A 35–90 days before the onset of their illness. None of the persons had significant risk factors for HCV infection within the typical incubation period (15–160 days before onset of symptoms), and five of the cases had procedures on the same day (September 21, 2007). The genetic relatedness of the viruses from case patients who had procedures on September 21, 2007, supports the epidemiologic findings and points to a common source of infection. The lack of genetic relatedness to the patient seen in July 2007 suggests a separate transmission incident. The two distinct clusters suggest patient-to-patient transmission rather than staff-to-patient transmission.

Most outbreaks of health-care–associated HCV have involved patient-to-patient transmission attributed to unsafe injection practices (*3,5*). The reuse of syringes and needles or mishandling of medication vials usually have been implicated (*6–8*). In some situations, syringes or needles used on HCV-infected persons were directly reused on other persons. In other instances, syringes or needles used on HCV-infected persons were reused to draw medication from a vial from which medicine was then drawn and administered to multiple persons, as was found in this investigation.

When gross errors or high-risk infection-control breaches that could lead to bloodborne pathogen transmission are recognized, including unsafe injection practices, potentially exposed persons should be notified and tested, even if transmission has not been confirmed (*9*). Those persons who are found to be infected can then obtain proper medical care. In addition to approximately 40,000 notifications that occurred as a result of this outbreak, in unrelated incidents, unsafe injection practices at three other outpatient clinics in two states have resulted in approximately 28,000 patient notifications during the preceding year (CDC, unpublished data, 2008). These situations could have been avoided if standard infection-control precautions, which include basic safe injection practices, had been followed (Box) (*10*).

This outbreak highlights the importance of surveillance and investigation in detecting viral hepatitis transmission in health-care settings. Prevention of transmission in these settings requires understanding and adherence to recommended infection-control practices. Medical and nursing school curricula and other health-care professional training, licensing, and continuing education requirements should include infection-control content, including the safe handling and administration of parenteral medications, as areas of competency. Although hospitals employ infection-control professionals and regularly evaluate infection-control practices, such oversight might be limited in outpatient settings that are not associated with hospitals. As use of these settings grows, appropriate methods will be

**BOX. Injection safety recommendations**

- Never administer medications from the same syringe to more than one patient, even if the needle is changed.
- Consider a syringe or needle contaminated after it has been used to enter or connect to a patients' intravenous infusion bag or administration set.
- Do not enter a vial with a used syringe or needle.
- Never use medications packaged as single-use vials for more than one patient.
- Assign medications packaged as multi-use vials to a single patient whenever possible.
- Do not use bags or bottles of intravenous solution as a common source of supply for more than one patient.
- Follow proper infection-control practices during the preparation and administration of injected medications.

Adapted from: CDC. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007. Atlanta, GA: US Department of Health and Human Services, CDC; 2007. Available at http://www.cdc.gov/ncidod/dhqp/gl_isolation.html.

needed to provide similar oversight for outpatient clinics. Better surveillance, education, and oversight are needed to detect and prevent bloodborne pathogen transmission in ambulatory and other health-care settings.

## References


1. Patel PR, Larson AK, Castel AD, et al. Hepatitis C virus infections from a contaminated radiopharmaceutical used in myocardial perfusion studies. JAMA 2006;296:2005–11.
2. CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47(No. RR-19).
3. Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. Clin Infect Dis 2004;38:1592–8.
4. CDC. Surveillance for acute viral hepatitis—United States, 2006. MMWR 2008;57(No. SS-2).
5. Alter MJ. Healthcare should not be a vehicle for transmission of hepatitis C virus. J Hepatol 2008;48:2–4.
6. CDC. Transmission of hepatitis B and C viruses in outpatient settings—New York, Oklahoma, and Nebraska, 2000–2002. MMWR 2003;52:901–6.
7. Comstock RD, Mallonee S, Fox JL, et al. A large nosocomial outbreak of hepatitis C and hepatitis B among patients receiving pain remediation treatments. Infect Control Hosp Epidemiol 2004;25:576–83.
8. Krause G, Trepka MJ, Whisenhunt RS, et al. Noscomial transmission of hepatitis C virus associated with the use of multidose saline vials. Infect Control Hosp Epidemiol 2003;24:122–7.
9. CDC. Steps for evaluating an infection control breach. Atlanta, GA: US Department of Health and Human Services, CDC; 2007. Available at http://www.cdc.gov/ncidod/dhqp/bp_steps_for_eval_ic_breach1.html.
10. CDC. Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings 2007. Atlanta, GA: US Department of Health and Human Services, CDC; 2007. Available at http://www.cdc.gov/ncidod/dhqp/gl_isolation.html.


# Use of Enhanced Surveillance for Hepatitis C Virus Infection to Detect a Cluster Among Young Injection-Drug Users — New York, November 2004–April 2007

Infection with hepatitis C virus (HCV) is a leading cause of chronic liver disease in the United States (*1*). Chronic hepatitis B and C virus infections were added to the nationally notifiable diseases list in 2003 (*2*). Approximately 3.2 million persons in the United States have chronic HCV infection (*3*). The most common risk factor for HCV infection is illicit drug use (specifically injection-drug use [IDU]) (*3,4*), although approximately one third to one half of cases have no identified risk factor (*4*; New York State Department of Health [NYSDOH], unpublished data, 2008). Because approximately 80% of acute HCV infections are asymptomatic and no serologic markers for recent infection exist, distinguishing recent from distant infection based on serology alone is challenging (*5*) and establishment of national HCV infection incidence is difficult. CDC provides funding to enhance surveillance for HCV infection and other forms of viral hepatitis in New York State (NYS) and seven other areas. One project of enhanced surveillance is to identify those HCV infections most likely to have been acquired recently. Since January 2006, NYSDOH has prioritized follow-up of positive laboratory markers for HCV infection among persons aged <30 years because they are more likely to be newly infected than older persons (*6*). In February 2007, NYSDOH detected a cluster of HCV infections among persons in this age group by using the prioritized algorithm. This report describes the subsequent investigation by NYSDOH and the Erie County Department of Health (ECDOH), which identified a group of patients with histories of IDU who were linked through a single high school that all the patients had attended at some time. The findings demonstrate how targeted enhanced surveillance can effectively detect clusters and outbreaks and guide appropriate interventions.

In 2004, the enhanced viral hepatitis surveillance project was launched in 34 of the 57 NYS counties outside of New York City. Detection and follow-up of reports of newly identified persons with HCV infections among NYS residents are given high priority to 1) collect accurate risk factor data, 2) guide prevention efforts, and 3) ensure patient referral to appropriate treatment. NYSDOH hepatitis surveillance staff members prioritize for immediate investigation any positive laboratory reports for markers of HCV infection among persons aged <30 years. Each week, the NYSDOH

**TABLE. Demographic characteristics, risk factors, surveillance status, and clinical information for 20 patients with hepatitis C virus (HCV) infection — postal code A, Buffalo, New York, November 2004–April 2007***

| Case | Interviewed | Age (yrs) | Sex | Race | Date of diagnosis | Reason for test | IDU† | Shared needles | Noninjection-drug use |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Yes | 17 | Male | White | 11/3/04 | Risk factors | Yes | Yes†† | Yes |
| 2 | No | 23 | Female | White | 1/25/05 | Symptomatic | Yes | — | Yes |
| 3 | No | 26 | Male | White | 3/9/05 | Risk factors | Yes | — | — |
| 4 | Yes | 28 | Male | White | 12/6/05 | Symptomatic | Yes | Yes | Yes |
| 5 | Yes | 17 | Male | White | 12/29/05 | Risk factors | Yes | Yes†† | Yes |
| 6 | No | 19 | Male | White | 1/20/06 | Symptomatic | Yes | Yes†† | Yes |
| 7 | Yes | 17 | Male | White | 1/24/06 | Risk factors | Yes | Yes†† | Yes |
| 8 | Yes | 16 | Female | White | 2/17/06 | Risk factors | Yes | Yes†† | Yes |
| 9 | Yes | 21 | Male | White | 2/23/06 | Risk factors | Yes | Yes†† | Yes |
| 10 | No | 22 | Male | White | 3/2/06 | Risk factors | Yes | — | — |
| 11 | Yes | 18 | Female | White | 5/17/06 | Risk factors | Yes | Yes | Yes |
| 12 | Yes | 19 | Male | White | 5/24/06 | Risk factors | Yes | Yes | Yes |
| 13 | No | 19 | Male | White | 5/24/06 | Risk factors | Yes | — | — |
| 14 | No | 20 | Male | White | 5/26/06 | Symptomatic | Yes | Yes†† | Yes |
| 15 | Yes | 17 | Female | White | 8/14/06 | Risk factors | No | No | No |
| 16 | Yes | 23 | Male | White | 10/10/06 | Risk factors | Yes | Yes†† | Yes |
| 17 | No | 19 | Male | White | 12/19/06 | Risk factors | Yes | Yes†† | Yes |
| 18 | No | 26 | Female | White | 1/6/07 | Risk factors | Yes | Yes | Yes |
| 19 | No | 17 | Female | White | 3/13/07 | Risk factors | Yes | Yes†† | Yes |
| 20 | Yes | 19 | Male | White | 4/26/07 | Risk factors | Yes | Yes†† | Yes |

* Data were compiled from standard surveillance forms and patient interviews.
† Injection-drug use.
§ Alanine aminotransferase.
¶ Based on surveillance case definitions (available at http://www.cdc.gov/ncphi/disss/nndss/casedef/hepatitiscacutecurrent.htm and http://www.cdc.gov/ncphi/disss/nndss/casedef/hepatitisccurrent.htm).
** Polymerase chain reaction.
†† Shared needles with a person known or believed to be HCV positive.
§§ Not reported.
¶¶ With a partner known or believed to be HCV positive.
*** With a sex worker.

Electronic Clinical Laboratory Reporting System generates databases containing any HCV-positive laboratory reports for persons aged <30 years; these data are then sent to local health departments. Investigation is conducted by local health department staff members with NYSDOH assistance and includes complete laboratory results collection, health-care provider interview, medical record review, and patient interview.

In February 2007, NYSDOH staff members noticed an apparent high number of newly identified HCV infections among persons aged <30 years who resided in the same postal code (postal code A), corresponding to a suburban community of Buffalo, New York. An initial retrospective review found eight cases dating back to May 2006 in persons who resided in postal code A (case numbers 11–18) (Table), one of which was in a patient who had acute hepatitis C (*7*). All but one of the eight initially identified cases were in persons who reported a history of IDU. Further analysis of cases in persons residing in postal code A indicated that during November 2004–April 2007, a total of 20 HCV-positive persons aged <30 years had been reported. Fifteen of the 20 cases were diagnosed in 2006 or 2007. The community (2000 population: 42,000) in which postal code A is located is part of Erie County and had 47.5 new reports of HCV infection per 100,000 population aged <30 years during November 2004–April 2007. During the same period, Erie County had 18.6 new reports of HCV infection per 100,000 population; two suburban postal codes with similar populations, socioeconomic composition, and proximity to the inner city as the investigated community had 7.0 and 4.9 new reports of HCV infection per 100,000 population, respectively. Because the incidence of new

**TABLE. (*Continued*) Demographic characteristics, risk factors, surveillance status, and clinical information for 20 patients with hepatitis C virus (HCV) infection — postal code A, Buffalo, New York, November 2004–April 2007***

| Case | History of incarceration | History of high-risk sexual contact | Drug equipment sharing or high-risk sexual activity with another patient (patient no.) | Multiple sex partners | Attended high school A | Jaundice (at time of diagnosis) | Elevated ALT§ (at time of diagnosis) | Disease status¶ | HCV PCR** (genotype) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Yes | No | Yes (9) | Yes | Yes | No | —§§ | Chronic | + (1B) |
| 2 | — | Yes¶¶ | No | Yes | Yes | Yes | Yes | Acute | + |
| 3 | — | — | No | — | Yes | No | — | Chronic | — |
| 4 | No | Yes*** | No | Yes | No | Yes | Yes | Acute | + |
| 5 | No | Yes¶¶ | Yes (8) | — | Yes | No | — | Chronic | + |
| 6 | Yes | — | Yes (7,16) | Yes | Yes | Yes | Yes | Acute | + |
| 7 | Yes | No | Yes (6,16) | Yes | Yes | No | — | Chronic | + |
| 8 | No | Yes¶¶ | Yes (5) | Yes | Yes | No | Yes | Chronic | + |
| 9 | Yes | Yes¶¶ | Yes (1) | Yes | Yes | No | Yes | Chronic | + |
| 10 | — | — | No | — | Yes | No | Yes | Chronic | + |
| 11 | No | Yes¶¶ | No | — | Yes | No | Yes | Chronic | + |
| 12 | Yes | No | No | Yes | Yes | No | — | Chronic | — |
| 13 | — | — | No | — | Yes | No | No | Chronic | — |
| 14 | — | — | No | Yes | Yes | No | Yes | Acute | — |
| 15 | No | No | No | No | Yes | No | No | Chronic | — |
| 16 | Yes | No | Yes (6,7) | Yes | Yes | No | No | Chronic | — |
| 17 | — | — | Yes (20) | Yes | Yes | No | Yes | Chronic | + (1A) |
| 18 | — | Yes¶ | No | Yes | Yes | No | Yes | Chronic | + (1A) |
| 19 | — | — | No | Yes | Yes | No | Yes | Chronic | + |
| 20 | No | No | Yes (17) | Yes | Yes | No | — | Chronic | + |

reports in the community per population appeared to be approximately twice that of the county and approximately six times greater than that of any similar suburb, further investigation to characterize the cluster was warranted.

With initial detection of the cluster, an epidemiologic investigation was launched by NYSDOH in collaboration with ECDOH. Patients were interviewed in person by a two-person team at various locales, including correctional facilities, rehabilitation clinics, patient residences, and other locations. Current CDC case definitions for acute and chronic hepatitis C were used.* Four (20%) of the 20 patients had evidence of elevated serum alanine transaminase levels and discrete symptom onset and were classified as having acute hepatitis C. Sixteen (80%) other patients were asymptomatic or had illness that did not meet the acute case definition and were classified as having chronic HCV infection. Median age of the 20 patients was 19 years (range: 17–29 years), all were white, 15 (75%) were male, and 19 (95%) reported a history of IDU. Nineteen (95%) of the 20 patients attended or had attended one of the two high schools in postal code A (high school A) (Table). Fourteen (70%) had evidence of viremia by polymerase chain reaction; three (21%) of these 14 had a viral genotype reported. NYSDOH and ECDOH staff members successfully interviewed 11 of the 20 patients (one with acute hepatitis C and 10 with chronic HCV infection) using an integrated interview tool and a chart abstraction tool developed for this investigation; the remaining nine patients could not be contacted.

At the time of interview, all of the 11 interviewed patients were aware that they had tested HCV positive. However, three (27%) of the patients interviewed believed that their test results were false and that they were no longer (or never were) HCV infected. Ten (91%) interviewed patients reported previous but not current IDU (including use of heroin, cocaine, loritabs, oxycodin, morphine, valium, or crack cocaine) and sharing of drug-use equipment; some patients shared equipment with other identified patients. All 10 patients reported purchasing heroin in the same inner-city Buffalo location. Noninjectable-drug use, reported by 10 (91%) patients, was initiated at a median age of 14 years (range: 9–17 years); IDU was initiated at a median age of 16.5 years (range: 14–26 years).

*Case definitions available at http://www.cdc.gov/ncphi/disss/nndss/casedef/hepatitiscacutecurrent.htm and http://www.cdc.gov/ncphi/disss/nndss/casedef/hepatitisccurrent.htm.

At least four partnerships involving drug equipment sharing and high-risk sexual activity were reported among the 20 patients. The members of these partnerships knew other members who had experienced symptoms consistent with acute hepatitis, such as jaundice. However, documented HCV infection in these members, as evidenced by a report in the NYSDOH Chronic Hepatitis Registry, could not be verified.

Among interviewed patients, median reported number of lifetime sex partners was 10 (range: four to 100). Six (54%) patients claimed they had private health insurance, two reported having Medicaid, and three reported that they had no health insurance. Seven of the interviewed patients reported having a primary-care physician; four of these seven reported seeing a specialist for their HCV infection. None of the interviewed patients had received HCV treatment. Several barriers to potential treatment were cited, including concerns regarding the side effects of medication, lack of information regarding the availability of treatment services, lack of health insurance reimbursement, and a perceived lack of health-care providers capable or willing to treat HCV in patients with comorbidities such as IDU or mental health issues.

Several initiatives were launched by NYSDOH and ECDOH throughout Erie County to address the apparent clustering of HCV infection among injection-drug users. Staff members from NYSDOH, the NYS Office of Alcoholism and Substance Abuse Services, and ECDOH conducted cross-training sessions and developed a resource manual to help identify primary care, sexually transmitted disease (STD)/human immunodeficiency virus (HIV) screening, drug treatment, harm reduction, and HCV treatment services for patients. All interviewed patients were referred to ECDOH counselors for HIV/acquired immunodeficiency syndrome (AIDS) risk assessment and personalized intervention development. ECDOH conducted multiple events held at various community locations and ECDOH clinics, offering HCV, HIV, and STD screening, referral for services, and education on prevention, risk reduction, and family planning; these services are ongoing at all five ECDOH clinics. Presentations on hepatitis epidemiology, diagnosis and testing, and prevention were conducted at medical practices that serve high-risk communities throughout Erie County. ECDOH also collaborated with the Erie County Department of Mental Health to integrate HCV messages into existing prevention programs and implement screening programs in target areas with high HCV infection rates. Finally, ECDOH worked with school district representatives and high schools to address prevention of IDU and HCV transmission.

**Reported by:** *L Leuchner, H Lindstrom, PhD, GR Burstein, MD, Erie County Dept of Health, Buffalo; KE Mulhern, EM Rocchio, MA, G Johnson, MS, J Schaffzin, MD, PhD, P Smith, MD, New York State Dept of Health.*

**Editorial Note:** One goal of the CDC-funded enhanced viral hepatitis surveillance protocols is high-priority follow-up of cases that are likely to represent acute HCV infection. Another goal is detection of clusters or outbreaks of such cases, as this report describes. The markedly elevated number of new reports of HCV infection per population detected among persons aged <30 years in postal code A, compared with the number of reports in the surrounding community, indicated an apparent cluster of recently infected patients. Nearly all of the identified patients in the cluster reported a history of IDU, and partnerships involving drug equipment sharing, which have been described previously (*8*), were identified among the cluster. The cause of this cluster likely was IDU with shared, inadequately cleaned equipment. Because the investigation targeted only cases in persons aged <30 years, more direct links among members of this cluster involving persons aged ≥30 years might exist within the community. Furthermore, although infections identified in persons aged <30 years are more likely to be new infections than those identified in persons aged ≥30 years, not all infections in the population aged <30 years are new; a portion of the patients in this cluster likely had been infected with HCV for years.

Although the number of new reports of HCV infection per population in postal code A was higher than the overall Erie County number during November 2004–April 2007, this analysis could not determine whether this elevated number of reports represented a previously established and ongoing higher rate of HCV infection among persons aged <30 years or a more recent phenomenon. Cases within this apparent cluster likely are a reflection of the ongoing HCV epidemic among injection-drug users in the United States (*9*). Ongoing educational efforts and increased public awareness of hepatitis C, particularly among injection-drug users, might have led to higher rates of testing, which yielded additional reports. Because the prioritized algorithm was not in place before January 2006, earlier reported cases of HCV infection among this population might have gone unrecognized. Continued enhanced surveillance is needed to complement routine surveillance for HCV infections to better understand the burden of hepatitis C and to identify and prevent new HCV infections.

The results of this investigation demonstrate the potential for improved and consistent national hepatitis C surveillance to identify cases for investigation, estimate the magnitude of HCV infection and disease, detect outbreaks,

evaluate response measures, and facilitate research to initiate appropriate prevention measures. Given limited resources, an enhanced surveillance approach to give highest priority to likely new cases of HCV infection, such as those in persons aged <30 years, can be implemented to identify clusters and outbreaks. Establishing effective systems that provide reliable data to detect HCV infections among all populations could have a lasting effect on HCV disease control.

**Acknowledgments**

This report is based, in part, on contributions by C Moore, Erie County Dept of Health; L Isabella, K Kufel, R Furlani, I Jones, New York State Dept of Health.

**References**

1. Rustgi VK. The epidemiology of hepatitis C infection in the United States. J Gastroenterol 2007;42:513–21.
2. CDC. Changes in National Notifiable Diseases list and data presentation. MMWR 2003;52:9.
3. Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Int Med 2006;144:705–14.
4. CDC. Surveillance for acute viral hepatitis—United States, 2006. MMWR 2008;57(No. SS-2).
5. Marcellin P. Hepatitis C: the clinical spectrum of the disease. J Hepatol 1999;31(Suppl 1):9–16.
6. Garfein RS, Vlahov D, Galai N, Doherty MC, Nelson KE. Viral infections in short-term injection drug users: the prevalence of the hepatitis C, hepatitis B, human immunodeficiency, and human T lymphotropic viruses. Am J Public Health 1996;86:655–61.
7. Council of State and Territorial Epidemiologists. Position statement 03-ID-05. Available at http://www.cste.org/ps/2003pdfs/2003finalpdf/03-id-05revised.pdf.
8. Hahn JA, Page-Shafer K, Lum PJ, et al. Hepatitis C virus seroconversion among young injection drug users: relationships and risks. J Infect Dis 2002;186:1558–64.
9. Edlin BR, Carden MR. Injection drug users: the overlooked core of the hepatitis C epidemic. Clin Infect Dis 2006;42:673–6.

## Multistate Outbreak of Human *Salmonella* Infections Caused by Contaminated Dry Dog Food — United States, 2006–2007

During January 1, 2006–December 31, 2007, CDC collaborated with public health officials in Pennsylvania, other states, and the Food and Drug Administration (FDA) to investigate a prolonged multistate outbreak of *Salmonella enterica* serotype Schwarzengrund infections in humans. A total of 70 cases of *S.* Schwarzengrund infection with the outbreak strain (XbaI pulsed-field gel electrophoresis [PFGE] pattern JM6X01.0015) were identified in 19 states, mostly in the northeastern United States. This report describes the outbreak investigation, which identified the source of infection as dry dog food produced at a manufacturing plant in Pennsylvania. This investigation is the first to identify contaminated dry dog food as a source of human *Salmonella* infections. After handling pet foods, pet owners should wash their hands immediately, and infants should be kept away from pet feeding areas.

On May 8, 2007, the Pennsylvania Bureau of Laboratories reported three cases of *S.* Schwarzengrund infection with indistinguishable PFGE patterns to CDC's PulseNet.* On June 9, 2007, after PulseNet identified cases in Ohio and other states, CDC's OutbreakNet† team was notified of a potential multistate outbreak of *S.* Schwarzengrund infections. During June 2007, the Pennsylvania Department of Health (PADOH) interviewed persons identified by PulseNet as infected with the outbreak strain of *S.* Schwarzengrund. These initial interviews suggested exposure to dogs or dry dog food as a possible source of infection. Thirteen infected persons from Pennsylvania were questioned about dog-related exposures: eight (62%) owned one or more dogs, and the other five reported regular contact with a dog. Seven of the eight persons who owned dogs were able to recall the types of dog food they had purchased recently. Several brands had been purchased, but persons in the households of six patients recalled purchasing dog food products made by manufacturer A. These interviews suggested exposure to dogs or dry dog foods as a possible source of infection.

PADOH collected dog stool specimens and opened bags of dry dog food from the homes of the 13 Pennsylvania patients. The outbreak strain of *S.* Schwarzengrund was isolated from five of 13 dog stool specimens and two of 22 dry dog food specimens collected from the homes. The contaminated dry dog food bags were two different brands (brand A and brand B), both produced by manufacturer A at plant A in Pennsylvania.

In July 2007, the Ohio Department of Health also interviewed persons infected with the outbreak strain of *S.* Schwarzengrund and collected two dog stool specimens from one patient's home. The outbreak strain of *S.* Schwarzengrund was isolated from one of the dog stool specimens. The dog recently had been fed brand A dry dog food, but the bag of dog food was no longer available for testing.

* PulseNet is the national molecular subtyping network for foodborne disease surveillance.
† OutbreakNet is a national network of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States.

**FOR IMMEDIATE RELEASE**
**October 23, 2008**

## Health District identifies 105 potential clinic-associated hepatitis C infections

**LAS VEGAS –** The Southern Nevada Health District has classified 101 cases of chronic hepatitis C infection as possibly associated with the Endoscopy Center of Southern Nevada, 700 Shadow Lane, and four cases possibly associated with the Desert Shadow Endoscopy Center, 4275 Burnham Avenue. The number of hepatitis C cases directly linked to the clinics remains at nine.

To date, the health district has received 7,331 Hepatitis C Exposure Registry enrollment forms since its implementation in June. Information received by contacting patients with positive laboratory reports and patients who were part of the case investigations were also entered into the registry database.

Laboratory confirmed patients with verified procedure dates, no identified risk factors and no history of positive laboratory reports were classified as "possibly associated." The health district classified 35 laboratory confirmed cases as "indeterminate" if the patient reported having one or more of the risk factors associated with hepatitis C infections. This classification does not rule out possible infection at the clinic. However, the health district cannot make any further determination because of the presence of other likely sources of infection.

The evaluation of chronic hepatitis C infections involves examining a patient's risk over a lifetime. The evaluation of acute hepatitis C infections involves examining a patient's risk for six months prior to the onset of symptoms. To evaluate patients' risk factors and to determine if their infection was related to the clinic, the health district developed a set of criteria to classify cases based on whether they were chronic or acute. In addition, classifications about the likelihood that the patient was exposed at the clinic were developed to help investigators better understand patient risk factors prior to having a procedure at the clinic.

"The registry, the interviews, and the criteria developed to identify and classify cases provided the investigators with important information to help us better understand the scope of this outbreak. This is the largest disease investigation that our health district has undertaken and we recognize the importance of sharing these results with the community," said Dr. Lawrence Sands, chief health officer. "The identification of these additional cases as well as the identification of the source cases from July and September reinforces our longstanding recommendation for patients of the clinic to get tested for possible infections."

-more-

In July, the health district reported that it identified two source cases related to the Endoscopy Center of Southern Nevada outbreak. One patient had a procedure on July 25, 2007, and the other on September 21, 2007. These are the dates that disease transmission was known to occur.

Results of genetic testing allowed the health district's epidemiology team to positively identify the two individuals as the source cases among clusters of patients who underwent procedures on the same dates. Samples were tested by the Centers for Disease Control and Prevention (CDC).

Information about the hepatitis C outbreak, including the health district's Interim Report on the outbreak, is available on the website, www.SouthernNevadaHealthDistrict.org.

-30-

STATE OF NEVADA

**JIM GIBBONS**
*Governor*

**MICHAEL J. WILLDEN**
*Director*

**RICHARD WHITLEY, MS**
*Administrator*

**MARY GUINAN, MD, PhD**
*State Health Officer*

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
HEALTH DIVISION
4150 Technology Way, Suite 300
Carson City, Nevada 89706
Telephone: (775) 684-4200 · Fax: (775) 684-4211

## Recognizing the Components of Nevada's Health Care System: In Response to the Hepatitis C Outbreak

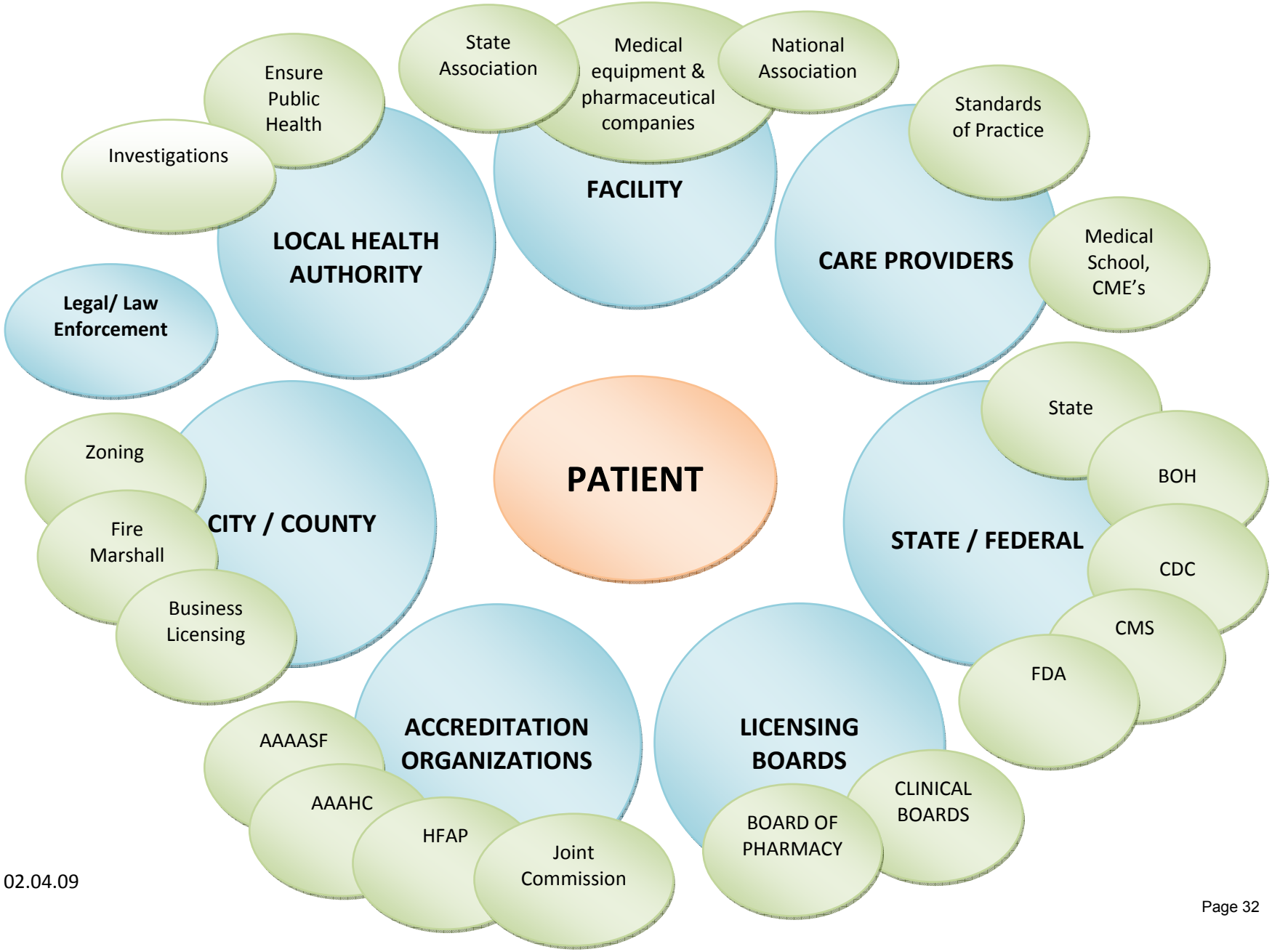
*A Necessary Step for Ensuring Patient Safety with Regard to Infection Control*

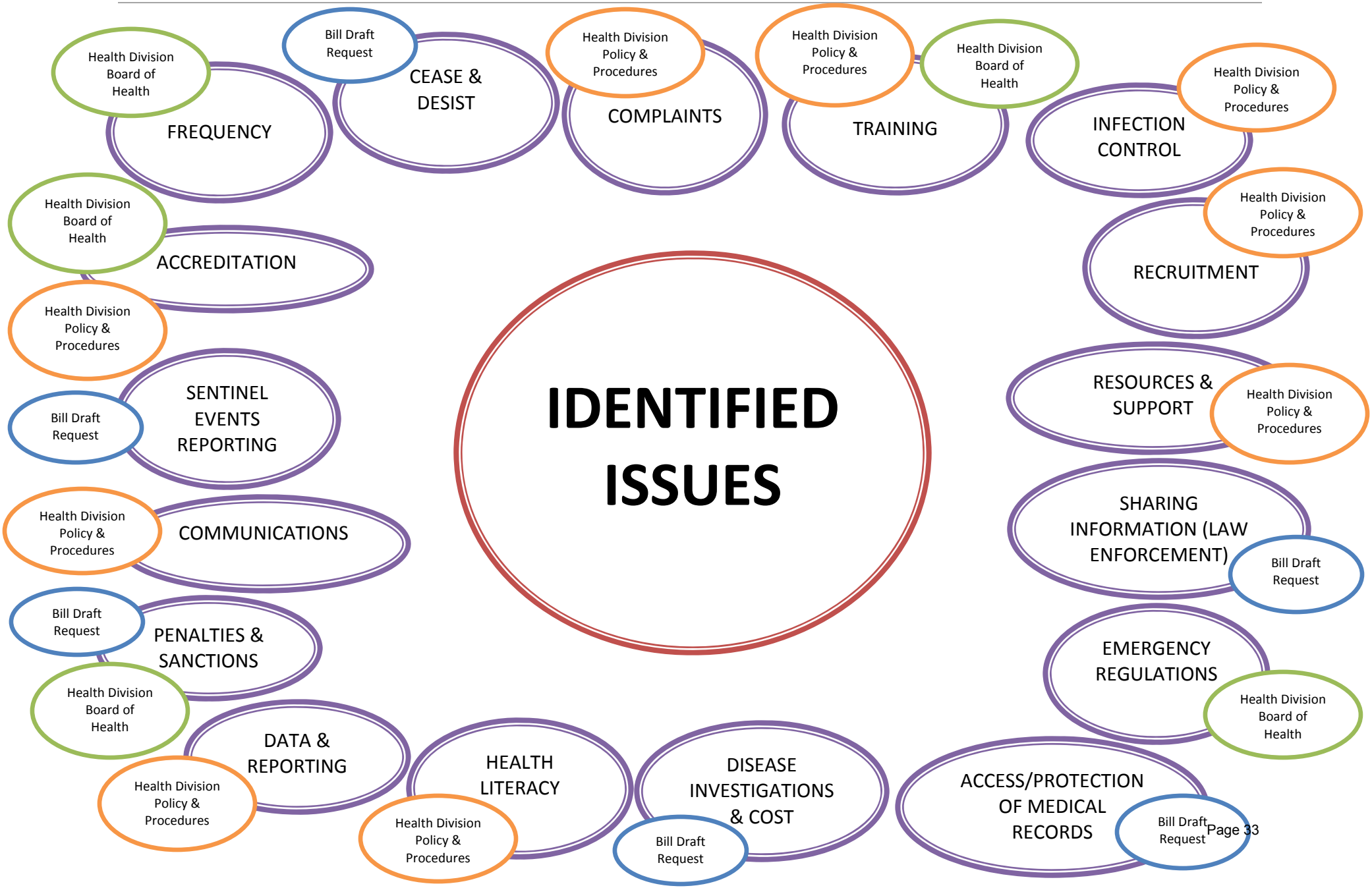
Mary Guinan, MD, PhD, State Health Officer

In 2005 report from the Institute of Medicine of the National Academy of Sciences entitled "To Err is Human" the expert committee outlined how medical errors occurred in health care settings. The authors point out that health care is a system which includes a vast network of health care professionals. Medical errors were often attributed to a "systems failure", i.e., some part of the network failed. In order to correct medical errors then they suggested a systems approach to prevention of medical errors. The great barrier to this is that the US health care system is too complex to understand who is responsible for what and that no clear lines of accountability existed. Therefore the authors suggested that what we have in the United States is a "non system of health care".

In 2008 in Las Vegas NV, Southern Nevada Health District revealed a Hepatitis C outbreak in Las Vegas linked to endoscopy centers. Federal, state and local public health investigators linked the outbreak to unsafe injection practices. Further investigation showed that the problem was clearly a "systems problem" for the Health Care/Public Health system in Nevada with failures at multiple levels. Therefore Nevada needed a "systems" approach to prevention. How can we ensure that this never happens again in Nevada? The Health Division started to examine all of the agencies and individuals in Nevada that were part of this system and what went right and what went wrong that resulted in the Hepatitis C outbreak. The State has primacy in matters of health and the State is responsible for understanding what the system is. The Health Division created what was called a **"bubble chart"** to identify all the agencies and individuals and their interactions and where the system failed to protect the patient and where were the lines of accountability. No other state to our knowledge has identified the components of their complex health system. This is the first "bubble chart" in attachment which is entitled "Recognizing the Components of Nevada's Health Care System: In Response to the Hepatitis C Outbreak". The following "bubble chart" is the "Systems Response to Prevent Blood Borne Infections in Medical Facilities". The following pages show a listing of the various issues that arose during the Hepatitis C Investigation and the approach to solving the problems.

As this "systems" approach was further studied it became clear that the framework of the system was solid but the components of the system may vary slightly depending on the problem being addressed.


Ensure Public Health
State Association
Medical equipment & pharmaceutical companies
National Association
Investigations
FACILITY
Standards of Practice
LOCAL HEALTH AUTHORITY
CARE PROVIDERS
Medical School, CME's
Legal/ Law Enforcement
Zoning
PATIENT
State
BOH
Fire Marshall
CITY / COUNTY
STATE / FEDERAL
CDC
CMS
Business Licensing
FDA
AAAASF
ACCREDITATION ORGANIZATIONS
LICENSING BOARDS
AAAHC
CLINICAL BOARDS
HFAP
BOARD OF PHARMACY
Joint Commission


IDENTIFIED ISSUES
FREQUENCY
Health Division Board of Health
CEASE & DESIST
Bill Draft Request
COMPLAINTS
Health Division Policy & Procedures
TRAINING
Health Division Policy & Procedures
Health Division Board of Health
INFECTION CONTROL
Health Division Policy & Procedures
RECRUITMENT
Health Division Policy & Procedures
RESOURCES & SUPPORT
Health Division Policy & Procedures
SHARING INFORMATION (LAW ENFORCEMENT)
Bill Draft Request
EMERGENCY REGULATIONS
Health Division Board of Health
ACCESS/PROTECTION OF MEDICAL RECORDS
Bill Draft Request
DISEASE INVESTIGATIONS & COST
Bill Draft Request
HEALTH LITERACY
Health Division Policy & Procedures
DATA & REPORTING
Health Division Policy & Procedures
PENALTIES & SANCTIONS
Health Division Board of Health
COMMUNICATIONS
Bill Draft Request
SENTINEL EVENTS REPORTING
Health Division Policy & Procedures
ACCREDITATION
Bill Draft Request
Health Division Board of Health

| Issues: | Bill Draft Request: Related to Enhancing Authority over Medical Facilities in Nevada |
|---|---|
| **Cease & Desist** | Allow the State Board of Health to adopt regulations to specify the conditions under which a medical facility can be closed during an on-going investigation. |
| **Penalties and Sanctions** | Clarify statutory language as it relates to the power of the Health Division to fine medical facilities for violations. |
| **Access/Protection of Medical Records** | (a) Give authority to the Health Division to take control over a facilities medical records in the event the facility is closed during the course of an investigation.<br>(b) Strengthen the authority of local health authorities or officers of health districts to subpoena records related to an on-going investigation of a medical facility. |
| **Sentinel Events Reporting** | Clarify statutory language related to sentinel events and establish penalties for facilities that do not report a sentinel event. |
| **Disease Investigations & Cost Recovery** | Clarify statutory language as it relates to the powers of local health authority or officer of a health district during disease investigations and establish methods to cover the costs of such disease investigations. |
| **Sharing Information (Law Enforcement)** | Clarify the method by which information in an investigation is shared with law enforcement authorities. |

| Issues: | Regulation: State of Nevada Health Division Board of Health |
|---|---|
| **Emergency Regulations** | Emergency regulations were approved by the State Board of Health on June 20, 2008 and signed off by the Secretary of State. |
| **Frequency** | Require that all facility types have a state frequency. Eighteen month periodicity proposed in budget - requesting an additional 14 positions. Eleven Health Facility Surveyors, One Biostatistician, One Management Analyst and One Administrative Assistant. |

| Issues: | Policy & Procedures: State of Nevada Health Division |
|---|---|
| **Complaints** | Health Division has revised the Health Division website and made it user-friendly to educate and better serve the public by providing a "no wrong door" approach to complaint reporting and patient safety education. Additionally, the bureau has created a listserv.<br><br>Changing the way we communicate with complainants so they don't have to wait for a Statement of Deficiency (SOD) to be issued but will receive a phone call and a letter outlining what we did to look into their compliant.<br><br>Working with other professional licensing boards on ways to do joint investigations on complaints.<br><br>Working on establishing an on-call, intermittent work force to do complaints, including working with the Community Health Nurses in rural areas to do some initial investigations. |
| **Recruitment, Staffing & Structure** | Health Division, Human Resources has implemented many of the strategies proposed in the recruitment plan prepared in March 2008. As of January 14, 2009, there are no vacant Health Facility Surveyor positions. The vacancy rate over the past ten months has gone from 25.7% to 0%. HR is now focused on retention issues and strategic planning for the future. Three contract positions have been filled to focus on complaint investigations as well as a systems analyst. |
| **Training** | Health Division has partnered with Southern Nevada Area Health Education Centers (AHEC) and developed internet-based standard infection control curriculum based on CDC guidelines. |

| Issues: | Policy & Procedures: State of Nevada Health Division |
|---|---|
| **Health Literacy Education** | Health Division has partnered with the State Medical Association to initiate a patient safety campaign in Nevada utilizing the HonoReform methodology and concepts. Campaign launch date is scheduled for February 11, 2009. |
| **Data & Reporting** | Health Division staff have been working on the standardization of medical facility data collection, the annual medical facility data report and the standardization of the statement of deficiency reports. The annual report will be released in February 2009.<br><br>Health Division has partnered with the State of Arizona to replicate their electronic posting software capabilities for statement of deficiencies – this will streamline Statement of Deficiency (SOD) postings. The posting will be done electronically versus the current manual input.<br><br>Health Division has been issuing press releases to keep the public informed on how emerging facility issues are being addressed. |
| **Infection Control** | The State Health Officer, Nevada Advisory Committee on Infection Control will be releasing recommendations by March 2009.<br><br>Require focused infection control survey, standardization of infection control procedures and the use of a standardized infection control tool.<br><br>Certified Infection Control Health Facilities Surveyor has been hired to focus on infection control policy and procedures and to train Division and facility staff.<br><br>Health Division has partnered with Southern Nevada Health District and the Association of Infection Control Professionals in a statewide Infection Control Symposium to be held in April 2009. The target audience will be infection control professionals from Skilled Nursing Facilities and smaller acute care hospitals. |
| **Communications** | Health Facility Surveyor work performance standards have been revised to include the following language: Immediate notification to local health authority when a procedure or practice is identified that is a risk for patient exposure to bloodborne pathogens; immediate notification to licensing board when practice or procedure by a licensed medical provider is determined to be a factor in risk or harm to a patient; and business licensing authority notification just prior to issuing the Statement of Deficiency (SOD) to the provider if bloodborne pathogen or other significant infection control risk was identified. |
| **Resources & Support** | Health Division ongoing resource and support of local health authorities:<br>Financial assistance concerning the hepatitis C investigation; Bi-monthly epi team meetings; Monthly health officer meetings; and State Epidemiologist liaison activities between health authorities and the Centers for Disease Control (CDC). |
| **Accreditation** | The Health Division has established a Memorandum of Agreement with the largest accrediting body and is in the process of negotiating with the remaining to formalize reciprocal communications. |

# STATE BOARD COMPLAINT PROCEDURES

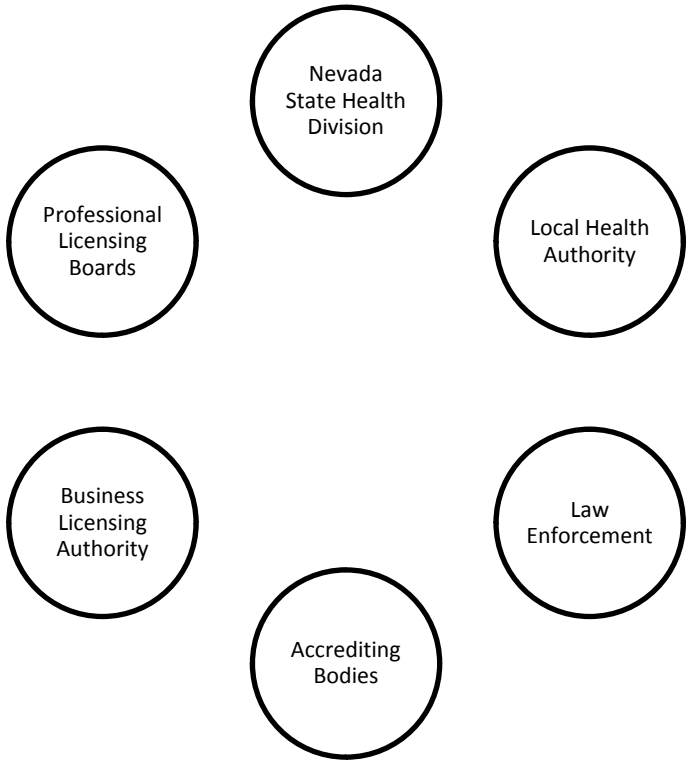
| ENTITY | HOW CAN A COMPLAINT BE FILED? | IS A SPECIFIC FORM REQUIRED TO FILE A COMPLAINT? | HOW CAN THE FORM BE OBTAINED? | SIGNATURE OR NOTARIZATION REQUIREMENT: | ADDITIONAL REQUIREMENTS FOR FILING A COMPLAINT: | SUPPORTING DOCUMENTS: | ARE ANONYMOUS COMPLAINTS ACCEPTED? |
|---|---|---|---|---|---|---|---|
| **Board of Medical Examiners (BOME)** | In writing.<br><br>Address:<br>PO Box 7238<br>Reno, NV 89510<br><br>Phone: 775-688-2559 | Yes. | Download from website. | The written complaint requires a signature. | | The complaint should also include any documentation which supports the complaint. | No, all complaints require a signature. |
| **Board of Nursing (BON)** | In writing.<br><br>Address:<br>5011 Meadowood Mall Way, #300<br>Reno, NV 89502-6547<br><br>Phone So.: 702-486-5800<br>Phone No.: 775-688-2620 | Yes OR a signed, written description of the sequence of events (who, what, where, when, why, how) may be submitted. | Download from website, through the SBN offices in Reno and Las Vegas or by calling the consumer hot line at 1-888-590-6726. | The written complaint must be signed by the complainant. | The complaint must include the name of the nurse and a detailed description of the alleged behavior which violates the Nurse Practice Act. | The complaint should also include any documentation which supports the complaint. | No, by law, the SBN cannot act on anonymous complaints. |
| **Board of Osteopathic Medicine (BOM)** | In writing.<br><br>Address:<br>2860 East Flamingo Road, Ste. D<br>Las Vegas, NV 89121<br><br>Phone: 702-732-2147 ext. 223 (Catryna Kelly) | Yes. | Form is not available for download on website. You must email osteo@bom.nv.gov. to request a complaint form. | The written complaint will not be accepted unless signature is notarized. | | | No, all complaints require a notarized signature. |
| **Board of Podiatry (BOP)** | In writing.<br><br>Address:<br>PO Box 12215<br>Reno, NV 89510-2215<br><br>Phone: 775-789-2605 | Yes. | Download from website. | The written complaint will not be accepted unless signature is notarized. | An Authorization to Release Information Form must also be included and requires a witness signature. | The complaint should also include any documentation which supports the complaint. | No, all complaints require a notarized signature. |

# Nevada State Health Division
# Communication Exchange with Various Partners
# PAST & PRESENT

## PAST

### Pre-Hepatitis C Outbreak

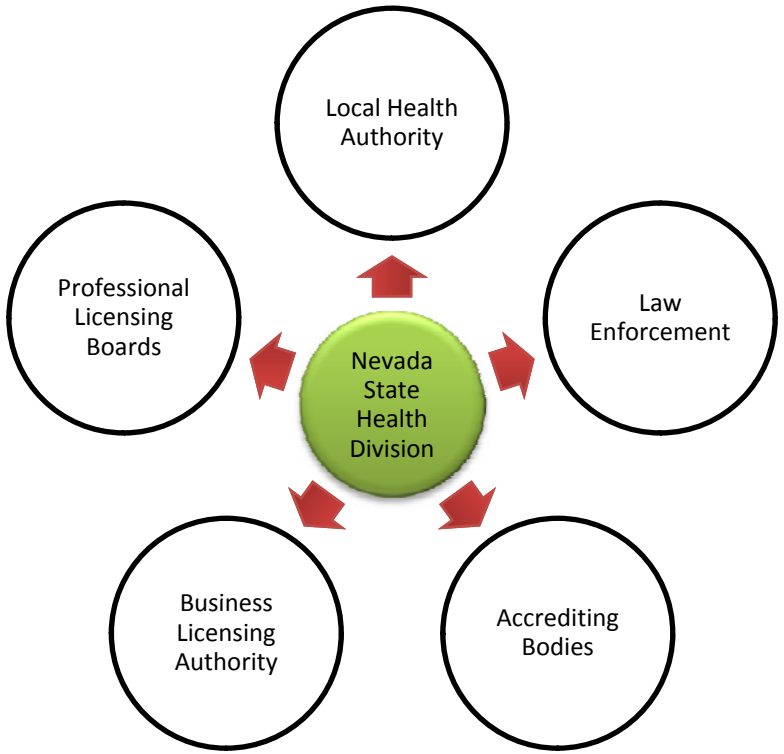
No formal communication channels




## PRESENT

### Health Division's Response during Hepatitis C Outbreak

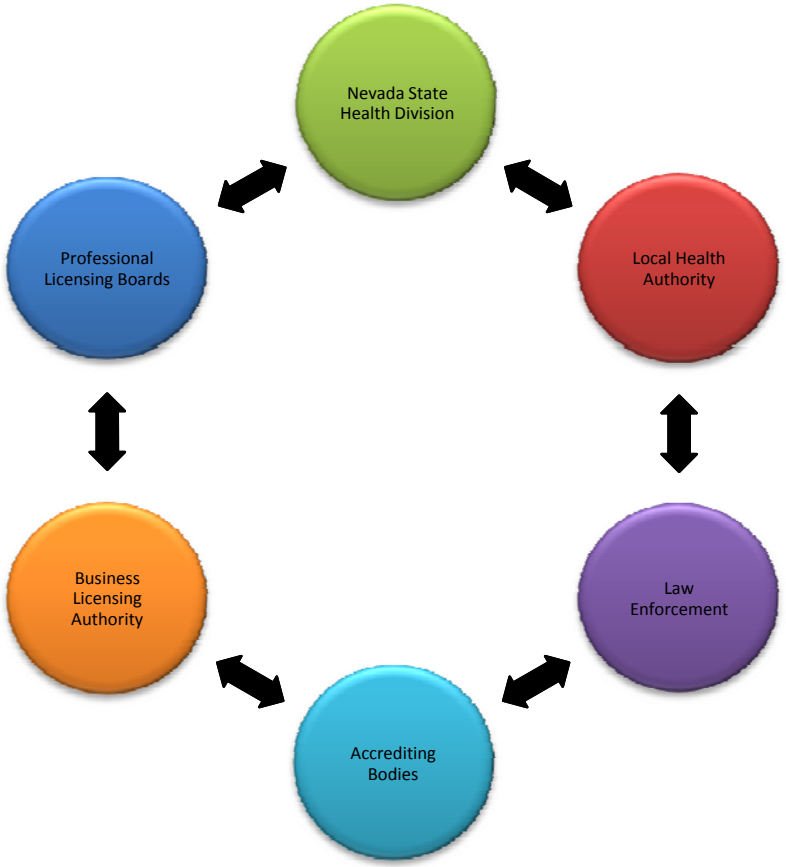
Communication channels established

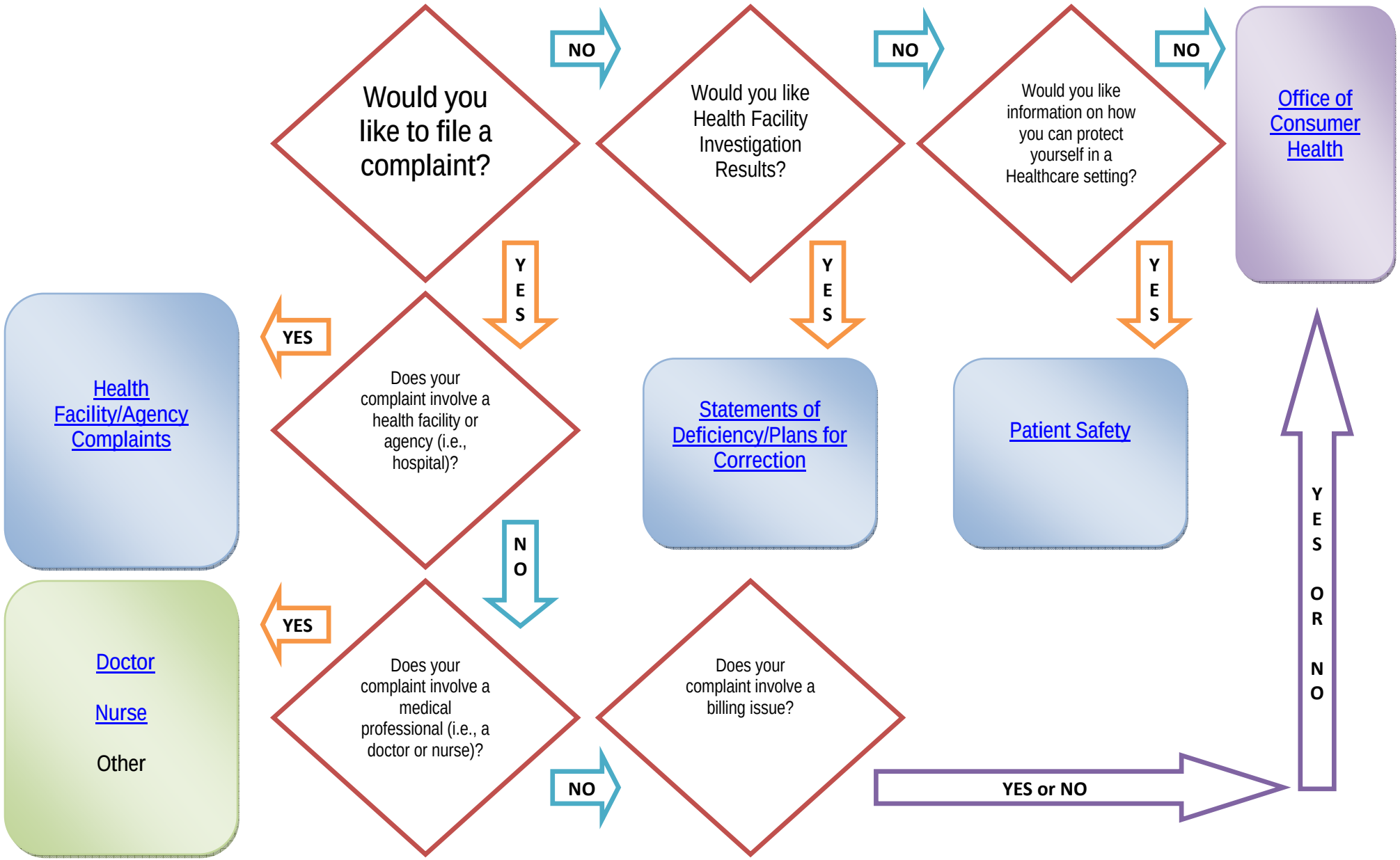


# Nevada State Health Division
# Communication Exchange with Various Partners
# **FUTURE**

## Policy Recommendations

Multi-agency communication channels functioning




Would you like to file a complaint?
NO
Would you like Health Facility Investigation Results?
NO
Would you like information on how you can protect yourself in a Healthcare setting?
NO
Office of Consumer Health
YES
YES
YES
Does your complaint involve a health facility or agency (i.e., hospital)?
YES
Health Facility/Agency Complaints
Statements of Deficiency/Plans for Correction
Patient Safety
NO
YES
Doctor
Nurse
Other
Does your complaint involve a medical professional (i.e., a doctor or nurse)?
NO
Does your complaint involve a billing issue?
YES or NO
YES OR NO

# Nevada State Health Division
# Technical Bulletin

**Topic: Hepatitis C Investigation** **Section/Program:**
**Bulletin Number: Epi February 2008** **State Epidemiologist, Dr. Azzam**

**TO: All Health Care Providers**

## *Potential Exposure to Hepatitis C (HCV) in an Ambulatory Surgical Center in Las Vegas*

*This technical bulletin and provider update summarizes our findings and actions, and provides recommendations and advice*

Through recent routine and active surveillance efforts, the Southern Nevada Health District Office of Epidemiology staff identified six cases of acute hepatitis C (HCV) infections. All six cases had undergone endoscopic procedures at the same ambulatory surgical center in Las Vegas in July and September 2007. Unsafe injection practices primarily reuse of syringes, and subsequent multi-use of single-dose medication vials, may have led to contamination of the vials and patient-to-patient transmission of the hepatitis C virus.

Health care related exposures are a well recognized but uncommon source of viral hepatitis transmission in the United States. Similar to this outbreak, the majority of outbreaks identified previously nationwide have been associated with unsafe injection practices, primarily reuse of syringes and needles or contamination of medication vials used for multiple patients. However, because of the long and variable incubation period and the fact that the majority of patients with HCV infection are asymptomatic, clusters of patients related to a specific healthcare setting might not be recognized.

When health care workers do not adhere to fundamental principles related to safe injection practices, it suggests that they fail to understand the potential for disease transmission. In addition, deficiencies related to oversight of personnel and failures to report breaches in infection-control practices result in delays in correcting the implicated practices. We believe that this outbreak could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications.

To prevent transmission of bloodborne pathogens, all healthcare workers should adhere to recommended standard precautions and fundamental infection control principles, including safe injection practices and appropriate aseptic techniques.

Injections are very safe when standard procedures are followed. Nevada State Health Division recommends the development of written up-to-date policies and procedures to prevent patient-to-patient transmission of bloodborne pathogens. Additionally these policies and procedures should be established and implemented among all staff involved in direct patient care.

Nevada State Health Division strongly advises that physicians and other health care providers in the state undergo mandated education periodically in proper infection control procedures. When

Approved by: _____
Dr. Ihsan Azzam, State Epidemiologist, Nevada State Health Division

**TO: All Health Care Providers**

renewing their licenses, physicians should acknowledge completing such training within the past four years.

Nevada State Health Division is partnering with professional organizations, advisory groups, and is working closely with SNHD and CDC to address these issues.

## Injection safety

- Use a sterile, single-use, disposable needle and syringe for each injection and discard intact in an appropriate sharps container after use.
- Use single-dose medication vials, prefilled syringes, and ampules when possible. Do not administer medications from single-dose vials to multiple patients or combine leftover contents for later use.
- If multiple-dose vials are used, restrict them to a centralized medication area or for single patient use. Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient. Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised.
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.
- Use aseptic technique to avoid contamination of sterile injection equipment and medications.

Adapted from Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000–2002. MMWR 2003;52(38):901-906.

Approved by: _____
Dr. Ihsan Azzam, State Epidemiologist, Nevada State Health Division

**Richard Whitley**
**Administrator**

**State Health Officer**

**Contact Name: Martha Framsted**
**Phone Number: 775-684-4014**
**Date: March 3, 2008**


# NEVADA STATE HEALTH DIVISION

## NEWS RELEASE

### Patients Urged to Ask Questions Prior to Surgical Procedure

*Carson City* – The Nevada State Health Division is encouraging patients to be proactive about impending surgical procedures by asking their health care provider about office protocols and standards prior to receiving a surgical procedure. Prompted by the recent investigation into a Southern Nevada Ambulatory Surgery Center's (ASC) medical practices and as a way to help alleviate patient fears and anxiety regarding infection control practices at their selected facility, the State Health Division offers the following suggested questions a patient may ask their service provider:

- Can you assure me that I am safe in your facility from the transmission of communicable diseases?
- How does the staff at this facility conduct sterilization of diagnostic equipment after each patient use?
- Are single or multiple dose vials used at the facility? Are label instructions followed specifically?
- Are syringes and needles disposed of after each use?
- Has your facility ever received a complaint of the spread of an infectious disease to another patient as a result of staff practices?

Patients can also request a copy of the facility's Infection Control Policies. In addition, a patient can request a copy of the most recent federal survey or complaint survey (if any) conducted at the facility by the Nevada State Health Division's Bureau of Licensure and Certification by writing to:

Nevada State Health Division
Bureau of Licensure and Certification
4220 S. Maryland Parkway, Bldg. D, Ste. 810
Las Vegas, Nevada 89119
702.468.6515

You can also contact BLC via email: BLCweb@health.nv.gov

**--MORE--**

If you have questions or concerns about insurance coverage or about payment for testing related to this incident, contact the Nevada Division of Insurance at 1-888-872-3234.

**Facts About Ambulatory Surgery Centers and the Bureau of Licensure and Certifications Role**

- "Ambulatory Surgical Center" or "ASC" includes any facility that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.
- There are 50 ASCs licensed in Nevada. Approximately 30 of these facilities are located in Southern Nevada. Some of these primarily provide endoscopic procedures. Others provide more extensive surgeries, but only for patients that will not require more than 24 hours in recovery before leaving the facility.
- The Bureau of Licensure and Certification (BLC) conducts a licensure inspection of ASCs before the can accept patients. The purpose of the inspection is to determine if the facility meets construction requirements and state health care regulations. BLC may conduct Medicare certification inspections after a facility has accepted patients, or the facility may be inspected by an accrediting agency for Medicare certification. After these initial inspections, BLC conducts complaint investigations whenever there are alleged violations of regulatory requirements.
- The Centers for Medicare and Medicaid Services (CMS) contracts with BLC to conduct inspections of all health care facilities in Nevada. This contract prioritizes the inspections and has set the minimal inspection periods for ASCs at one inspection every six years.
- In 2007, BLC received a total of four ASC complaints. To date in 2008, BLC has received five ASC complaints. All complaints are prioritized and scheduled for investigation based on their priority.
- Following an investigation, an ASC is notified of any deficiencies. If the facility fails to make corrections, BLC may take action against the facility, including terminating the business's license if the facility fails to make corrections for compliance with federal Medicare regulations.

The State Epidemiologist, Dr. Ihsan Azzam, issued a technical bulletin to all ASCs and health care providers. The bulletin can be accessed by going to:
http://health.nv.gov/docs/hepctechnicalbulletin.pdf

###

**SUMMARY OF TIMELINE**

**FOR REGULATORY CHANGES RELATED TO INFECTION CONTROL**

**IN AMBULATORY SURGERY CENTERS**

| Regulation Number | Date | Summary of Regulation |
|---|---|---|
| Not Assigned | March 6, 2008 | EMERGENCY REGULATIONS<br>Provides for more specific wording for licensed surgical centers to make clear their requirement to ensure the safe delivery of medications and to establish effective programs for infection control |
| R096-08I | April 23, 2008 | INITIAL AGENCY DRAFT<br>Revises provisions governing surgical centers for ambulatory patients |
| R096-08P | June 19, 2008 | LCB PROPOSED DRAFT<br>Makes various changes concerning the operation of ambulatory surgical centers |
| R096-08A | August 26, 2008<br>Effective:<br>October 25, 2008 | ADOPTED<br>Makes various changes concerning the operation of surgical centers for ambulatory patients |

**ADOPTED REGULATION OF THE**

**STATE BOARD OF HEALTH**

**LCB File No. R096-08**

Effective October 25, 2008

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1-29, NRS 441A.120 and 449.037.

A REGULATION relating to ambulatory surgical centers; requiring ambulatory surgical centers to establish a program for the prevention and control of infections and communicable diseases; requiring the governing body of an ambulatory surgical center to adopt guidelines for the program; revising certain provisions relating to the administration of medication; revising certain provisions governing medications used at ambulatory surgical centers; revising the requirements for blood transfusions; and providing other matters properly relating thereto.

**Section 1.** Chapter 449 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 19, inclusive, of this regulation.

**Sec. 2.** ***"Biohazardous waste" means all biological waste or biologically contaminated waste that may cause harm to humans, animals or plants.***

**Sec. 3.** ***"Biologic indicator test" means a test used in every ethylene oxide cycle and in every sterilization load of implantable medical items to demonstrate through the destruction of highly resistant bacterial spores whether all parameters, including, without limitation, time, temperature, sterilant and humidity, were met to effectively sterilize the medical items.***

**Sec. 4.** ***"Cleaning" means the physical removal of organic material or soil from objects by using water, with or without detergents, that is designed to remove, rather than kill, microorganisms.***

**Sec. 5.** ***"High-level disinfection" means a type of disinfection which destroys all microorganisms with the exception of high levels of bacterial spores. Such disinfection may be accomplished through the use of processes that include, without limitation, boiling items in water, steaming items in water and soaking items in chemical disinfectants.***

**Sec. 6.** ***"Implantable device" means a medical device that is implanted in the human body, including, without limitation, a pacemaker, defibrillator, heart valve, hearing device or joint replacement.***

**Sec. 7.** ***"Invasive procedure" means a medical procedure involving entry into the human body by puncture or incision or by insertion of an instrument.***

**Sec. 8.** ***"Low-level disinfection" means a type of disinfection which eliminates most bacteria, some viruses and some fungi, but which may not kill resistant microorganisms. Such disinfection may be accomplished through the use of processes that include, without limitation, soaking items in chemical disinfectants.***

**Sec. 9.** ***"Multidose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions, contains:***

***1. More than one dose of a medication; and***

***2. May be used for one or more patients.***

**Sec. 10.** ***"Reprocess" means the process of subjecting a single-use medical device that has been previously used on a patient to additional cleaning, disinfection or sterilization, manufacturing steps, including, without limitation, repackaging and relabeling, and testing of the technical and functional safety of the device to make the device ready for safe use on another patient.***

**Sec. 11.** ***"Single-dose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions:***

***1. Contains only one dose of a medication; and***

***2. May be used for only one patient.***

**Sec. 12.** ***"Sterilization" means a process using medical equipment, including, without limitation, a dry heat sterilizer or an autoclave, to destroy all forms of microbial life.***

**Sec. 13.** ***1. The governing body shall adopt guidelines which must be used by the ambulatory surgical center in establishing the program for the prevention and control of infections and communicable diseases required pursuant to section 14 of this regulation.***

***2. The guidelines adopted pursuant to subsection 1 may include, without limitation, guidelines, statements or recommendations issued or published by other agencies or organizations, and must:***

***(a) Be based on evidence, theoretical rationale or scientific data; and***

***(b) Include well-designed experimental, clinical or epidemiological studies which document the processes used in the development of the studies and grade the strength of the evidence relied on in the studies.***

***3. The governing body shall ensure that a copy of the guidelines adopted pursuant to subsection 1 is available at the ambulatory surgical center and accessible to the staff of the ambulatory surgical center and the public.***

**Sec. 14.** ***1. Each ambulatory surgical center shall establish and maintain a program for the prevention and control of infections and communicable diseases.***

***2. In addition to complying with the provisions of sections 13 to 19, inclusive, of this regulation, a program for the prevention and control of infections and communicable diseases must be:***

***(a) Appropriate for the services provided at the ambulatory surgical center;***

***(b) Based on the guidelines adopted by the governing body pursuant to section 13 of this regulation; and***

***(c) Developed in a manner that takes into consideration:***

***(1) All the surgical and other medical services provided at the ambulatory surgical center;***

***(2) The types of patients typically treated at the ambulatory surgical center, including, without limitation, those whose age or medical condition makes them vulnerable to infections and communicable diseases;***

***(3) The types of injuries or illnesses typically treated at the ambulatory surgical center;***

***(4) The number of patients typically treated at the ambulatory surgical center;***

***(5) The level of education and training of the staff of the ambulatory surgical center;***

***(6) The number of nurses available at the ambulatory surgical center, the qualifications of such nurses and the amount of support required of the nurses by the physicians at the ambulatory surgical center;***

***(7) The types of invasive procedures performed at the ambulatory surgical center;***

***(8) The locations within the ambulatory surgical center where invasive procedures are performed;***

***(9) The specific medical instruments and equipment used at the ambulatory surgical center;***

*(10) The physical design of the ambulatory surgical center; and*

*(11) The causes, risks and patterns of infections and transmission of communicable diseases that arise in the setting of each medical procedure performed at the ambulatory surgical center.*

**Sec. 15.** *Each program for the prevention and control of infections and communicable diseases must include policies and procedures to prevent exposure to blood-borne and other potentially infectious pathogens, including, without limitation, policies and procedures relating to:*

*1. Hand hygiene, including provisions regarding the time and procedure for handwashing with soap and water or use of an alcohol-based hand rub.*

*2. The proper use of medical gloves. Those policies and procedures must, at a minimum, provide that each person who works at the ambulatory surgical center must wear medical gloves when the person:*

*(a) Anticipates coming in contact with blood or bodily fluids;*

*(b) Handles contaminated instruments, items and equipment;*

*(c) Handles biohazardous waste;*

*(d) Handles linens potentially contaminated with biohazardous waste; and*

*(e) Performs housekeeping activities or cleans contaminated surfaces.*

*3. Safe injection practices to prevent the contamination of equipment used for injections and medication. Those policies and procedures must provide that a new sterile needle and new sterile syringe must be used for each patient and may not be used for more than one patient.*

*4. The proper handling of sharp instruments and the disposal of sharp instruments. Those policies and procedures must be consistent with the standards developed by the*

*Occupational Safety and Health Administration for the handling and disposal of such instruments.*

*5. Techniques for accessing a vial of medication. Those policies and procedures must comply with the requirements set forth in section 16 of this regulation.*

*6. The infusion of intravenous medications. Those policies and procedures must provide that intravenous tubing and fluid bags or bottles must not be used for more than one patient.*

*7. The proper sterilization and disinfection of all medical equipment, instruments and devices. Those policies and procedures must, at a minimum, require an ambulatory surgical center to:*

*(a) Sterilize or ascertain the sterility of items that enter sterile tissue or the vascular system, including, without limitation, surgical instruments, endoscopes, endoscopic accessories, catheters, needles and probes used for ultrasounds;*

*(b) Perform high-level disinfection of reusable items that come in contact with nonintact skin or mucus membranes, including, without limitation, respiratory therapy equipment, anesthesia equipment, bronchoscopes and gastrointestinal endoscopes; and*

*(c) Perform low-level disinfection of reusable items that come in contact with only intact skin, including, without limitation, tourniquets, blood pressure cuffs, linens, stands that are used to hold medical instruments and other furnishings.*

*8. The proper handling of equipment, instruments and devices. Those policies and procedures must, at a minimum, require an ambulatory surgical center to:*

*(a) Sterilize and disinfect reusable items as described in subsection 6;*

***(b) Properly dispose of single-use equipment, instruments and devices after use, if the ambulatory surgical center has decided not to have the equipment, instruments or devices reprocessed;***

***(c) Ensure that:***

***(1) All equipment, instruments and devices that may be reprocessed are reprocessed only by a third-party processor approved by the United States Food and Drug Administration; and***

***(2) No equipment, instruments or devices that may be reprocessed are reprocessed at the ambulatory surgical center.***

***9. The proper handling and disposal of medical waste and specimens.***

***10. The proper cleaning and disinfection of all areas in which patient care is provided.***

***11. The proper maintenance of a clean and sanitary environment.***

***12. The identification and reporting of the development and transmission of infections and communicable diseases. Those policies and procedures must include the method by which the ambulatory surgical center must:***

***(a) Track and document the development and transmission of infections and communicable diseases which are related to the medical procedures performed at the ambulatory surgical center;***

***(b) Report the development and transmission of infections and communicable diseases as required by federal, state and local laws; and***

***(c) Identify and address trends in such developments and transmissions of infections and communicable diseases.***

*13. The care of patients with a communicable disease, including, without limitation, patients who are known to have a communicable disease at the time of arrival at the ambulatory surgical center and patients who are found to have a communicable disease during the course of treatment at the ambulatory surgical center.*

*14. The screening for communicable diseases as described in NAC 441A.375 of all employees and of all persons under contract with the ambulatory surgical center who work at the center and have exposure to patients at the center.*

**Sec. 16.** *1. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for single-dose vials which provide that a single-dose vial may be accessed only by using an aseptic technique. The policies and procedures must provide that:*

*(a) Each injection of a medication from a single-dose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;*

*(b) The medication in a single-dose vial must not be used for more than one patient;*

*(c) A single-dose vial, including any remaining medication in the vial after its use, must be discarded; and*

*(d) Any remaining medication in a single-use vial after its use must not be combined with any other medication or otherwise used for any other patients.*

*2. Each program for the prevention and control of infections and communicable diseases must include policies and procedures for multidose vials which provide that a multidose vial may be accessed only by using an aseptic technique. The policies and procedures must provide that:*

*(a) The cap of a multidose vial must be cleaned with an alcohol-based wipe before the vial is accessed;*

*(b) A new sterile needle and new sterile syringe must be used each time to access a multidose vial;*

*(c) Upon first access of a multidose vial, the person who accessed the vial shall date and initial the vial;*

*(d) Each injection of a medication from a multidose vial must be prepared in a clean, designated area where contamination by blood or bodily fluid is unlikely to occur;*

*(e) A needle must not be left inserted in the cap of a multidose vial after its use; and*

*(f) A multidose vial must be discarded when the medication in the vial has expired or 28 days after the vial was initially accessed.*

**Sec. 17**. *1. All surgical instruments, items or equipment used in the care of patients at an ambulatory surgical center must be sterilized or disinfected according to the program for the prevention and control of infections and communicable diseases adopted by the ambulatory surgical center pursuant to section 14 of this regulation.*

*2. If such instruments, items and equipment are sterilized or disinfected by equipment or cleaning agents at the ambulatory surgical center:*

*(a) Before an employee or independent contractor may be assigned the responsibility for sterilizing or disinfecting any instrument, item or equipment, the employee or independent contractor must receive training concerning the instructions of the manufacturer of the device or sterilizer for:*

*(1) Sterilizing and disinfecting the instrument, item or equipment;*

*(2) The use and maintenance of the sterilizer or disinfecting equipment; and*

***(3) The agents used to sterilize and disinfect the instrument, item or equipment.***

***(b) An employee or independent contractor assigned the responsibility for sterilizing or disinfecting the instrument, item or equipment shall:***

***(1) Receive annual training concerning the manufacturer's instructions described in paragraph (a); and***

***(2) Receive training on any new equipment or procedures if there is any change in the equipment or procedures used to sterilize or disinfect an instrument, item or equipment.***

***(c) The ambulatory surgical center shall ensure that documentation of all training completed pursuant to this subsection is kept in the file of the employee or independent contractor.***

***3. The manufacturer's instructions for operating any sterilizer or performing any disinfection procedure must be located or posted near the equipment used for sterilization or disinfection.***

***4. The ambulatory surgical center shall ensure that each employee or independent contractor follows the manufacturer's instructions concerning:***

***(a) The instruments, items or equipment that may be sterilized or disinfected;***

***(b) The procedures for cleaning an instrument, item or equipment before the instrument, item or equipment is sterilized or undergoes high-level disinfection;***

***(c) The procedures for sterilizing or disinfecting an instrument, item or equipment;***

***(d) The operation and maintenance of the sterilizer or the equipment used for high-level disinfection;***

***(e) The frequency and type of biologic indicator testing of the sterilizer;***

*(f) The recommended agents for sterilizing and disinfecting the instrument, item or equipment; and*

*(g) The frequency of testing of any solution for disinfecting to ensure maintenance of the minimum level of effectiveness, but not less often than daily testing.*

*5. The effectiveness of the sterilization procedures must be checked by performing a biologic indicator test:*

*(a) At least weekly, or more frequently if recommended by the manufacturer; and*

*(b) While sterilizing all implantable devices.*

*6. Sterilization records and logs of the results of the biologic indicator test must be maintained by the ambulatory surgical center for at least 1 year after the test is performed to ensure that the recommended testing and maintenance of the equipment is performed and the manufacturer's instructions regarding proper sterilization techniques are followed. Each ambulatory surgical center shall establish a method to track and recall instruments, items or equipment previously sterilized or disinfected if there is a failure of the biologic indicator test.*

*7. To aid in environmental control, each ambulatory surgical center shall provide a physical barrier between the decontamination and sterilization areas of the ambulatory surgical center.*

**Sec. 18.** *1. Each ambulatory surgical center shall designate an employee or enter into a contract with a person to oversee and manage all aspects of the program for the prevention and control of infections and communicable diseases.*

*2. The person described in subsection 1:*

*(a) Shall have completed specialized training in the prevention and control of the development and transmission of infections and communicable diseases; and*

***(b) Shall ensure that the program for the prevention and control of infections and communicable diseases for the ambulatory surgical center:***

***(1) Complies with all applicable federal, state and local laws;***

***(2) Is consistent with the guidelines adopted by the governing body pursuant to section 13 of this regulation; and***

***(3) Is reviewed with all employees of the ambulatory surgical center and all persons under contract with the ambulatory surgical center who work at the center and have exposure to patients at the center within the first 10 days of employment and every 12 months thereafter, or more often if required pursuant to subsection 2 of section 19 of this regulation.***

**Sec. 19.** ***1. Each employee of an ambulatory surgical center and each person under contract with an ambulatory surgical center who works at the center and has exposure to patients at the center shall receive training and be evaluated by supervising staff on his knowledge and skills concerning the program for the prevention and control of infections and communicable diseases within the first 10 days of employment and at least every 12 months thereafter.***

***2. An employee or person under contract with the ambulatory surgical center may be required to receive the training and evaluation described in subsection 1 more often than every 12 months if his supervisor determines that such training and evaluations are necessary to ensure that he understands and will follow the policies and procedures of the program for the prevention and control of infections and communicable diseases.***

**Sec. 20.** NAC 449.971 is hereby amended to read as follows:

449.971 As used in NAC 449.971 to 449.996, inclusive, ***and sections 2 to 19, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC

449.9715 to 449.9743, inclusive, ***and sections 2 to 12, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

**Sec. 21.** NAC 449.9785 is hereby amended to read as follows:

449.9785 During the term of his license, the licensee shall continuously maintain the ambulatory surgical center in conformance with the provisions of NAC 449.971 to 449.996, inclusive ~~[.]~~ ***, and sections 2 to 19, inclusive, of this regulation.*** Any violation of these provisions may result in the suspension or revocation of the license.

**Sec. 22.** NAC 449.980 is hereby amended to read as follows:

449.980 The governing body shall ensure that:

1. Each patient of the center is under the care of a physician.

2. Each patient admitted to the center receives a presurgical evaluation conducted by a physician within the 7 days immediately preceding the date of his surgery.

3. A physician is on the premises of the ambulatory surgical center and immediately available at all times when there are patients in the operating rooms or the recovery room of the center. As used in this subsection, "immediately available" means the physician is sufficiently free from other duties to be able to respond rapidly to an emergency.

4. An annual operating budget and a plan for capital expenditures are established.

5. The center is adequately staffed and equipped.

6. There is documentation in the files of the center of ~~[the]~~ ***:***

***(a) The*** qualifications of all persons under contract with the center ~~[.]~~ ***; and***

***(b) Whether such persons who work at the center and have exposure to patients have been screened for communicable diseases as described in NAC 441A.375.***

7. ***The center establishes and maintains a program for the prevention and control of infections and communicable diseases as required pursuant to section 14 of this regulation.***

***8.*** The center adopts, enforces and ***at least*** annually reviews written policies and procedures required by NAC 449.971 to 449.996, inclusive, ***and sections 2 to 19, inclusive, of this regulation,*** including an organizational chart. These policies and procedures must:

(a) Be approved annually by the governing body.

(b) Provide that a surgical procedure may be performed on a patient only with the consent of the patient or his legal representative, except in an emergency.

(c) ~~[Include procedures for the isolation or immediate transfer of a patient with a communicable disease.~~

~~(d)]~~ Include procedures for the periodic review and amendment, as deemed appropriate, of the scope of the procedures performed at the center.

**Sec. 23.** NAC 449.9835 is hereby amended to read as follows:

449.9835 1. If a licensee is a physician operator, the ambulatory surgical center operated by the licensee is not required to have a governing body or an administrator. In such a case, in the absence of a governing body or an administrator, the physician operator is responsible for complying with all the provisions of NAC 449.971 to 449.996, inclusive ~~[.]~~ ***, and sections 2 to 19, inclusive, of this regulation.***

2. As used in this section, "physician operator" means a physician, a podiatric physician licensed pursuant to chapter 635 of NRS or a dentist licensed pursuant to chapter 631 of NRS

who is operating an ambulatory surgical center for the purpose of performing surgery only upon his patients.

**Sec. 24.** NAC 449.990 is hereby amended to read as follows:

449.990 1. Any medication or treatment may be given only upon the written or oral order of a person lawfully authorized to prescribe that medication or treatment. This order must be authenticated by the prescriber and the person administering the medication. An oral order must be recorded and authenticated within 24 hours after it is ~~[made.]~~ ***given.***

2. Medications prepared by one nurse may not be administered by another nurse.

3. At the time the medication is administered, the patient must be identified and the medication must be identified as being ordered for that patient and recorded in the medical record of the patient.

4. ~~[Records must be maintained for any substance listed as a schedule II controlled substance pursuant to chapter 453 of NRS. Any such record must indicate the name of the patient, the name of the prescriber, the name of the controlled substance, the strength and dose administered, and the balance of the controlled substance remaining. A count must be made of all such controlled substances at the change of each nursing shift by a nurse from each shift. The count must be authenticated by both nurses.~~

~~5. Transfusions of blood or intravenous]~~ ***Intravenous*** medications ***or fluids*** may be administered only by persons who have been specially trained and are authorized for that duty. ~~[An ambulatory surgical center shall adopt policies and procedures for the administration of blood.~~

~~6.]~~ ***5.*** Any suspected adverse reaction to a ~~[transfusion or]~~ medication must be reported by members of the nursing staff to the physician attending the patient. The nursing staff shall ~~[note]~~

***document*** the reaction in the medical record of the patient. ~~[Any suspected reaction to a transfusion must also be reported to the service that furnished the blood.]~~

***6. All medications must be prepared and administered in a safe and effective manner in accordance with the program for the prevention and control of infections and communicable diseases adopted pursuant to section 14 of this regulation and in accordance with the manufacturer's instructions.***

**Sec. 25.** NAC 449.9905 is hereby amended to read as follows:

449.9905 1. A pharmacist must be on the staff of each ambulatory surgical center or under contract with the center. ~~[He]~~ ***The pharmacist*** is responsible for all matters pertaining to the use of drugs in the center. ~~[If the center employs a part-time pharmacist by contract, he shall visit the center not less frequently than once each month. These visits must be documented.]~~

2. Records of all transactions must be in writing and maintained so the receipt and disposition of any drug may be readily traced.

3. Drugs requiring refrigeration must be stored in a locked refrigerator or a refrigerator in a locked room. ~~[Food must not be stored in this refrigerator except for food used as a vehicle for the administration of drugs.]~~

4. In the absence of a full-time pharmacist, the director of nursing must be designated in writing as responsible for the control of dangerous drugs and controlled substances. ~~[Substances listed as schedule II controlled substances pursuant to]~~ ***Controlled substances as described in*** chapter 453 of NRS must be stored in a storage area with two locks. If a box is used, it must be securely fastened and immovable. ***The keys or combinations to the locks must be accessible only to licensed health care professionals.***

5. ~~[Drugs may not be kept in stock after the expiration date on the label. Obsolete, contaminated or deteriorated drugs must be destroyed.]~~ ***All drugs must be logged into and checked out of stock only by a licensed health care professional.***

***6. The ambulatory surgical center shall obtain a license to operate a pharmacy pursuant to chapter 639 of NRS.***

**Sec. 26.** NAC 449.9925 is hereby amended to read as follows:

449.9925 1. If the ambulatory surgical center provides its own service for blood transfusions through its ~~[clinical laboratory:]~~ ***medical laboratory as defined in NRS 652.060:***

(a) Any arrangement for the procurement, safekeeping or transfusion of blood or derivatives of blood must be under the supervision of a ~~[physician.]~~ ***pathologist;***

(b) Any reaction to a transfusion of blood must be investigated ***;*** ~~[.]~~

(c) The storage equipment for blood and derivatives of blood must be protected by an alarm system which ~~[is]~~ ***must be*** tested each month ***and the temperature continuously monitored*** to ~~[check]~~ ***verify*** its operation ***;*** ~~[.]~~

(d) Samples of the blood of any patient receiving a transfusion and of each unit of blood used in the center must be retained in accordance with the written policy of the laboratory for at least 7 days for further testing in the event of a reaction to the transfusion ~~[.]~~ ***; and***

(e) Blood and derivatives of blood that have exceeded their expiration date ~~[may]~~ ***must*** not be used ~~[.]~~ ***and must be disposed of as biohazardous waste.***

2. If the ambulatory surgical center depends on an outside source for blood, there must be in force a written agreement governing the procurement of blood and derivatives of blood that is reviewed annually by the governing body and the staff pathologist or the pathologist used as a consultant by the center.

***3. Blood and derivatives of blood used in the ambulatory surgical center must be administered only by a physician or a registered nurse.***

***4. The ambulatory surgical center shall establish policies and procedures for the administration of blood and derivatives of blood that are in accordance with the program for the prevention and control of infections and communicable diseases adopted pursuant to section 14 of this regulation.***

***5. Any suspected adverse reaction to a blood transfusion must immediately be reported by members of the nursing staff to the physician attending the patient and to the service that furnished the blood. The nursing staff shall document the reaction in the medical history of the patient.***

**Sec. 27.** NAC 449.9895 is hereby repealed.

**Sec. 28.** Notwithstanding the provisions of sections 18 and 19 of this regulation, a person who, on October 25, 2008:

1. Is employed by an ambulatory surgical center as defined in NAC 449.972; or

2. Is under contract with an ambulatory surgical center as defined in NAC 449.972, works at the ambulatory surgical center and has exposure to patients at the ambulatory surgical center,

➥ is not required to satisfy the initial training requirements set forth in those sections until December 24, 2008.

**Sec. 29.** This regulation becomes effective on October 25, 2008.

## TEXT OF REPEALED SECTION

**449.9895 Sterilization. (NRS 449.037)**

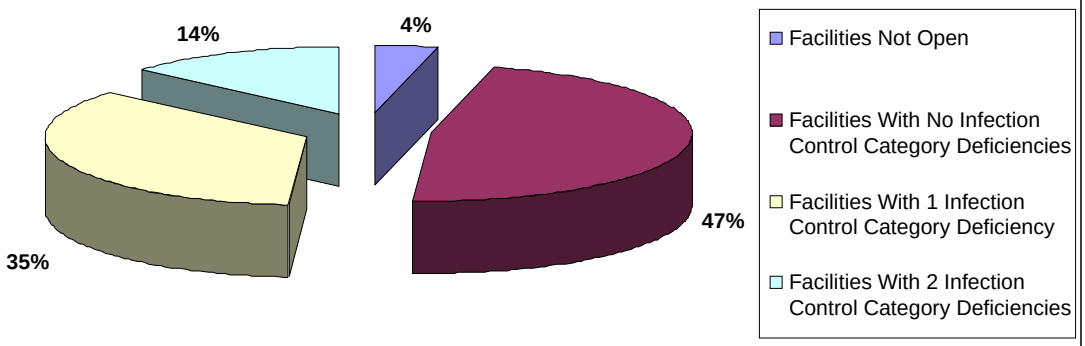
1. All surgical instruments, sutures and drains used in the care of patients must be sterile.

2. If these materials are sterilized on the premises, the process of sterilization must be supervised by a person who has received specialized training in the operation of that process, including training in methods of testing to verify the efficiency of the process.

3. Instructions for operating any autoclave or sterilizer must be posted near the equipment, and this equipment must be maintained in a safe operating condition.

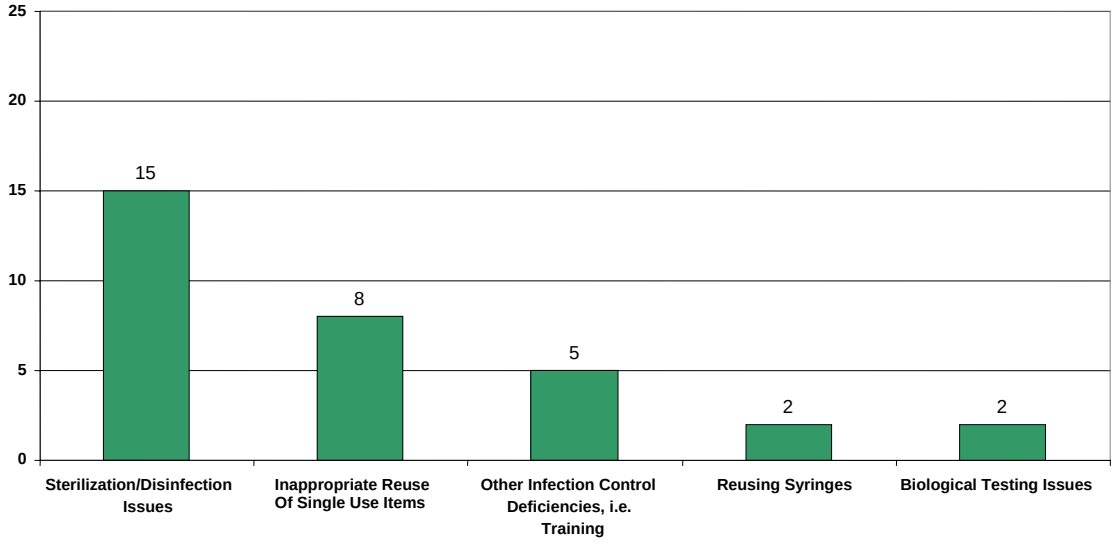
4. The efficiency of the method of sterilization used must be checked not less frequently than once each month by bacteriological tests. Records of the results of these tests must be maintained by the center for at least 1 year.

## Ambulatory Surgical Centers
## Infection Control Focused Surveys - 2008
## Facilities by Number of Infection Control Category Deficiencies




Note - Infection Control Categories are: Sterilization/Disinfection Issues, Reusing Single Dose Vials for Multiple Patients, Other Infection Control Deficiencies, Reusing Syringes, Biological Testing Issues

## Ambulatory Surgical Centers
## Infection Control Focused Surveys - 2008
## Number of Problems Identified



# INFECTION CONTROL SITE VISIT

## MODULE I
### GENERAL INFORMATION

1. Facility name: _____

2. Type of facility: (Please circle)
   a. Hospital
   b. SNF/NF
   c. ASC
   d. ESRD
   e. Rural Health Clinic
   f. NTC, CTCs, MDX
   g. Home Health Agencies
   h. Other _____

3. Date of site visit: _____ (MM/DD/YYYY)

4. Name of surveyor completing form: _____

5. Is facility accredited? A) Yes B) No

**If Answer to Q 5 is No, Please Skip to Q9**

6. If yes, please circle type:
   a). JCAHO
   b). AAAHC
   c). AAAASF
   d). AOA
   e). Other (specify)_____

7. Date accreditation expires: _____ (MM/DD/YYYY)

8. Is Facility Deemed: 1) Yes 2) No (Additional Criteria)

9. Types of surgical/procedures performed at the facility (circle all that apply):

   a. Cardiovascular
   b. Foot
   c. General Surgery
   d. Neurological
   e. OB, GYN
   f. Ophthalmology
   g. Oral
   h. Orthopedic
   i. ENT
   j. Plastics
   k. Thoracic

l. Urology
m. Pain Management
n. AV fistulas
o. None of the above
p. Other _____

10. If endoscopy procedures are performed
    a. Average number of procedures performed monthly _____
       List types and numbers of procedures (i.e. colonoscopy 15/mo)
       _____ ___ _____ ___

       _____ ___ _____ ___
    b. Number of individual scopes that the facility utilizes _____
       ___ Own? ___ Borrow? ___ Lease? If so, from whom? _____
       List types and numbers of scopes
       _____
    c. Does the facility have a system to identify which scope was used on which patient? ____ Yes ___ No
    d. Do you lend your scopes to any other facility or provider? ___ Yes ___ No
       If so provide detail _____
    e. Cleaning/Disinfection of scopes - Accomplished 100% manually?___ Yes ___ No
       Accomplished thru manual cleaning and automated reprocessor? ___ Yes___ No
       Sent out to another facility to be processed? ___ Yes ___ No
       Biological cultures are performed? ___ Yes ___ No
       If yes, On scopes? ___Yes___ No On automated reprocessor?___ Yes ___ No
    f. Training of scope reprocessor. _____ Hands on by another scope reprocessor _____ Attended formal training program (produce proof) _____ Hands on by certified trainer in scope reprocessing (provide proof) _____ Self taught _____ Other

| **Question** | **Observation/Documentation** | **Interview** |
|---|---|---|
| **MODULE II. INFECTION CONTROL PROGRAM** | **Circle Answer** | **Circle Answer** |
| 1. Does the facility have a comprehensive infection control program? | Yes No | Yes No |
| 2. Have the facilities infection control policies and procedures been reviewed and approved annually by the facilities governing body? | Yes No | Yes No |
| 3. What standard of practice is the facility following? (Circle all that apply) | a) Has a copy of standard<br><br>b) Does not have a copy of standard | a)CDC b) APIC<br>c)AORN d)SGNA<br>e) OSHA f) Other<br>g) Unable to state |

| | | |
|---|---|---|
| | | standard of practice |
| 4. Does the facility have a process to assure that staff is following the facility's infection control program? | Yes No | Yes No |
| 5. Does the facility have a process for tracking post-procedural infections? | Yes No | Yes No |
| 6. What kind of infection control surveillance is being conducted? | a) Surgical wounds<br>b) Procedure specific<br>c) Multi Drug Resistant Organisms (MDROs)<br>d) Bloodstream Infections<br>e) Foley assoc urinary tract infections<br>f) Other _____<br>g) No surveillance is being conducted | Yes No |
| Have any of the surveillance findings resulted in an outbreak investigation? | Yes No | Yes No |
| 7. Does the person in charge of infection control have formal infection control training? | Yes No | Yes No<br>Source_____ |
| 8. Does this person receive at least annual training updates? | Yes No | Yes No |
| 9. Does the facility provide at least annual infection control inservices to staff? | Yes No | Yes No |
| 10. How does the facility communicate infection control training/updates to staff? | a.) In-service (face-to-face)<br>b.) Computer training<br>c.) Other _____<br>d.) None | |

| | | | | |
|---|---|---|---|---|
| 11. Does the facility incorporate infection control into its quality assurance program? | Yes | No | Yes | No |
| **Comments:** | | | | |
| **Module III. Communicable Disease Control** | | | | |
| 1. Is there a policy and procedure<br>- for patients that are known to have a communicable disease on arrival?<br>- for patients who are found to have a communicable disease during the course of treatment at the facility? | Yes<br>Yes | No<br>No | Yes<br>Yes | No<br>No |
| 2. Does the facility have a current list of reportable communicable diseases from the public health authority? | Yes | No | Yes | No |
| 3. Is there an appropriate system for the reporting of reportable diseases? | Yes | No | Yes | No |
| 4. Does the facility have a policy and procedure in place to handle an employee that contracts a communicable disease?<br><br>**COMMENTS:** | Yes | No | Yes | No |
| **Module IV. Hand Hygiene** | **Observation/Documentation** | | **Interview** | |
| 1. Soap and water is easily accessible | Yes | No | | |
| | | | | |

| | | | |
|---|---|---|---|
| 2. Alcohol-based hand rub is easily accessible | Yes | No | |
| 3. Staff perform hand hygiene:<br>a. Before patient contact (even if gloves are worn).<br><br>b. After patient contact (even if gloves are worn).<br><br>c. After contact with potentially contaminated surfaces (even if gloves are worn). | Yes<br><br>Yes<br><br>Yes | No<br><br>No<br><br>No | |
| 4. Regarding gloves, staff:<br><br>a. Wear gloves for procedures that potentially involve contact with blood or body fluids.<br><br>b. Wear gloves when handling potentially/known contaminated patient equipment.<br><br>c. Remove soiled gloves before moving to next task. | Yes<br><br>Yes<br><br>Yes | No<br><br>No<br><br>No | |
| 5. If a surgical scrub is required, the surgical team performs *surgical hand scrub* in accordance with current infection control guidelines. | Yes | No | |
| **Comments:** | | | |

| **MODULE V. Injection Practices (including medications, saline, other infusates,** | **Observation/Documentation** | **Interview** |
|---|---|---|

| **IM, SQ, Epidurals, Spinals, etc.)** | | |
|---|---|---|
| 1. Needles and syringes are used for only one patient. | Yes No | Yes No |
| 2. Needles are handled using aseptic technique and do not come into contact with environmental surfaces. | Yes No | |
| 3. Injections are prepared in a clean, designated area that is free from contamination with blood, body fluids, or other visible contamination. | Yes No | Yes No |
| 4. Single dose medications/infusates are used for only one patient. **(If answer is c – skip to #6)** | (a) Yes (b) No or (c) Single dose vial was not used | (a) Yes (b) No or (c) Single dose vial was not used |
| 5. After opening, single dose vials are discarded when the manufacturers' recommended open time limit has been reached. | Yes No | Yes No |
| 6. Multi -dose vials/infusates are used in accordance with current infection control standards. **(If answer is c – skip to #11)** | (a) Yes (b) No or (c) Single dose vial was not used | (a) Yes (b) No or (c) Single dose vial was not used |
| **7.** A multi dose vial must be discarded when the medication in the vial has expired or 28 days after the vial was initially accessed. | Yes No | Yes No |

| | | |
|---|---|---|
| 8. Multi -dose vials are dated and initialed the day they are opened. | Yes No | Yes No |
| 9. Multi-dose vials are entered with a new, sterile needle and a new, sterile syringe. | Yes No | Yes No |
| 10. The cap of a multi dose vial must be cleaned with an alcohol-based wipe before the vial is accessed. | Yes No | Yes No |
| 11. Medications/infusates that are packaged as prefilled syringes are used for only one patient. | Yes No N/A | Yes No N/A |
| 12. Medications/infusates are drawn up at the start of each procedure. | Yes No | Yes No |
| 13. Fluid infusion and administration sets (e.g., intravenous bags, tubing and connectors) are:<br>a. Used for one patient only.<br>b. Disposed of after use.<br>c. Does not use a single IV bag to mix medications for more than one patient.<br>d. Tubing is changed every 48 to 72 hours.<br>e. IV bags are changed every 24 hours or sooner.<br>**If no central lines are used, SKIP to MODULE VI , Q1** | <br><br>Yes No<br>Yes No<br>Yes No N/A<br>Yes No N/A<br>Yes No N/A | <br><br>Yes No<br>Yes No<br>Yes No N/A<br>Yes No N/A<br>Yes No N/A |
| | | |

| | | | | |
|---|---|---|---|---|
| 14. Central lines are accessed with aseptic technique | Yes | No | Yes | No |
| **COMMENTS:** | | | | |
| **MODULE VI. Sterilization, High Level Disinfection, and Single Use Devices** | **Observation/Documentation** | | **Interview** | |
| 1. Are sterilization procedures performed on-site?<br>**If no, Skip to Q 7.** | Yes | No | Yes | No |
| 2. Are equipment/instruments and/or supplies sterilized according to the manufacturer's recommendation or current standards of practice? | Yes | No | Yes | No |
| 3. All critical equipment (i.e., items that enter sterile tissue or the vascular system) are sterilized appropriately:<br>a. Medical devices and instruments are | Yes<br>Yes | No<br>No | Yes<br>Yes | No<br>No |

| | | |
|---|---|---|
| decontaminated before packaging and sterilization<br>b. Enzymatic cleaners are used as directed by the manufacturer.<br>c. A quality indicator (e.g., chemical indicator) is placed in each load.<br>d. A biologic indicator is performed at least weekly.<br>e. A biological is run with every implant load.<br>f. Sterilization records and logs of results of biological indicator tests are kept up-to-date and maintained by the facility for one year.<br>g. The facility uses flash sterilization in accordance with current infection control guidelines. | Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No N/A | Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No<br>Yes No N/A |
| 4. There is a procedure in place for identification and recall of sterilized instruments that were not adequately sterilized. | Yes No | Yes No |
| 5. The sterilization equipment is being maintained according to manufacturer's direction. | Yes No | Yes No |
| 6. The maintenance log for all sterilization equipment is up-to-date | Yes No | Yes No |
| 7. Sterile packages are inspected for integrity and compromised packages are reprocessed. | Yes No | Yes No |

| | | | | |
|---|---|---|---|---|
| | | | | |
| 8. Sterile medical devices and instruments are stored so that sterility is not compromised. | Yes | No | Yes | No |
| 9. Semi-critical items (items that come in contact with non-intact skin or mucus membranes) receive at least high-level disinfection. | Yes | No | Yes | No |
| 10. Is high-level disinfection performed on-site?<br><br>**If no, Skip to Q 20** | Yes | No | Yes | No |
| 11. Medical devices and instruments are decontaminated before high-level disinfection | Yes | No | Yes | No |
| 12. High-level disinfection equipment is maintained according to manufacturer instructions. | Yes | No | Yes | No |
| 13. Chemicals used for high-level disinfection are prepared according to manufacturer instructions | Yes | No | Yes | No |
| 14. Chemicals used for high-level disinfection are tested according to manufacturer instructions and are replaced before they expire. | Yes | No | Yes | No |

| | | |
|---|---|---|
| 15. Logs for high-level disinfection chemical preparation indicate solution is prepared and replaced according to manufacturer instructions. | Yes No | Yes No |
| 16. Were the item(s) completely submerged in the high-level disinfecting solution? | Yes No | |
| 17. Sterilized equipment is maintained according to the manufacturer's direction. | Yes No | |
| 18. The maintenance logs for all sterilized equipment are kept up-to-date. | Yes No | Yes No |
| 19. Items that undergo high-level disinfection are dried before reuse. | Yes No N/A | Yes No |
| 20. Following high-level disinfection, items are stored in a manner to prevent contamination. | Yes No | Yes No |
| 21. A staff member(s) that has received specialized training in the sterilization and disinfection process is responsible for sterilization and maintenance of sterilization equipment. | Yes No N/A | Yes No N/A |
| 22. The facility has documented evidence of the specialized training. | Yes No N/A | |

| | | |
|---|---|---|
| 23. Does the facility reprocess single use items in the facility? NOTE: Only FDA approved reprocessors can reprocess single-use items.<br><br>a) If so, is a copy of the contract available to the surveyor? | Yes No N/A<br><br>Yes No N/A | Yes No N/A |
| **COMMENTS:** | | |
| **MODULE VII. Employee Health Program** | **Observation/Documentation** | **Interview** |
| 1. Do staff members use barrier/Standard precautions appropriately? | Yes No | Yes No |
| 2. Does an OSHA Bloodborne Pathogen Exposure Control Plan exist? | Yes No | Yes No |
| 3. Does the facility maintain a log of needlestick and sharps injuries? | Yes No | Yes No |
| 4. If the facility tracks such injuries, how many needle stick and sharps injuries have been documented in the past 12 months? | ___ 0, ___ 1 – 5 ___ 6 – 10<br>___ 11 – 15 ___ 16 – 20<br>___ more. No. of splashes ___ | Does not track |
| 5. Employee TB testing<br><br>– documentation of PPD (+)<br><br>- if (+), counseling and prophylaxis documented (by | Yes No<br><br>Yes No<br><br>Yes No | Yes No |

| | | |
|---|---|---|
| current employer or previous)<br>- annual assessments for those with documented (+) PPDs<br><br>- testing given to those with history of receiving BCG<br><br>- 2 step PPD given appropriately | Yes No<br><br>Yes No<br><br>Yes No | |
| 6. Staff members are offered<br>- annual influenza vaccine<br>- hepatitis B vaccine & f/u testing to "at risk" employees | Yes No<br>Yes No | Yes No<br>Yes No |
| **Comments:** | | |
| **MODULE VIII. Environmental Infection Control** | **Observation/Documentation** | **Interview** |
| 1. Objects and environmental surfaces in the operating room (e.g., bed, monitor cords, horizontal surfaces, medication preparation areas, etc.) are disinfected with an EPA-registered disinfectant(s) at the beginning of each surgery/procedure day, between each patient, and at the end of each day. | Yes No N/A | |
| 2. Anesthesia cart/work area is cleaned between patients with an EPA-registered disinfectant after each | Yes No | |

| | | |
|---|---|---|
| patient. | | |
| 3. Objects and environmental surfaces used on patients outside the OR – procedural tables, gurneys, beds, etc, are disinfected with an EPA registered disinfectant after each patient and daily. | Yes No | |
| 4. The disinfectant is used per manufacturer's guidelines to ensure effectiveness. | Yes No | Yes No |
| 5. Decontamination areas and clean areas are separated. | Yes No | |
| 6. Sterile items are stored in a clean area located away from contamination/dirty areas. | Yes No | |
| 7. Surgical and invasive procedure rooms are cleaned and disinfected after each patient. | Yes No | Yes No |
| 8. Reusable items that come into contact with only intact skin (e.g. BP cuffs) are cleaned between patients. | Yes No | Yes No |
| 9. All sharps are disposed of in a puncture-resistant sharps container. | Yes No | |
| 10. Sharps containers are located in appropriate areas and are secured and are easily accessible | Yes No | |
| 11. Sharp containers are replaced before the fill line is reached. | Yes No | |
| 12. Biohazardous waste is disposed of appropriately. | Yes No | Yes No |

| | | |
|---|---|---|
| **Comments:** | | |

| **MODULE IX. Glucometer disinfection between patients** | **Observation/Documentation** | **Interview** |
|---|---|---|
| 1. The facility uses the same glucometer on more than one patient. **Skip this section if facility does not utilize the same tool between patients** | Yes No | Yes No |
| 2. A new single use lancing device is used for each patient. | Yes No | Yes No |
| 3. Injection pens are used (Note: A "No" answer indicates NO breach in infection control) | Yes No | Yes No |
| 4. The patient's finger is disinfected prior to testing | Yes No | Yes No |
| 5. The glucometer is cleaned/disinfected between every patient. | Yes No | Yes No |